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Prescription Benefit Medication Prior Authorization Criteria for Large Group Commercial

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These criteria apply to drugs picked up at the pharmacy.

These medication prior authorization criteria do not apply to drugs picked up at the pharmacy for State and Local Government members or BadgerCare Plus and/or Medicaid SSI members.

State and Local Government members should call **Navitus** at **(866) 333-2757** or visit navitus.com for information about your prescription drug benefits.

Quartz BadgerCare Plus and/or Medicaid SSI members must call the **Wisconsin Department of Health and Family Services** at **(800) 362-3002** or visit forwardhealth.wi.gov for information about your prescription drug benefits.

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May 1, 2025
Pharmacy Benefit Drug
Prior Authorization Criteria for Large Group Commercial

A medication prior authorization request may be started by members, providers, or designated representatives by fax, electronically on Quartz's website, telephone, mail. Or, for medical benefit medications, also by Health Link, Plan Link, MyQuartzTools, or electronic prior authorization (e-PA) within the electronic medical record. Electronic (e-PA) via Surescripts verifies member eligibility and member benefit information. Quartz sends back e-PA criteria questions to the provider staff which can be answered, and medical records can be attached to the request.

Quartz strongly recommends that the health care provider initiate the prior authorization request process on behalf of the member. This is because the health care provider will be able to include the medical history necessary for a timely decision to be made based on all of the relevant information, including any case specific circumstances that can be considered. Once a request and the supporting documentation have been submitted, a pharmacist or appropriate staff review the prior authorization criteria and exception requirements separately to make a coverage decision.

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Prior Authorization Guideline

Guideline ID	GL-228339
Guideline Name	5-Aminosalicylates - PA, ST
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Asacol HD (mesalamine delayed-release)
Ulcerative colitis Indicated for the treatment of moderately active ulcerative colitis in adults. Limitations of Use: Safety and effectiveness of Asacol HD beyond 6 weeks have not been established.
Drug Name: Delzicol (mesalamine delayed-release)
Treatment of mildly-moderately active ulcerative colitis Indicated for the treatment of mildly to moderately active ulcerative colitis in patients 5 years of age and older. **Maintenance of remission of ulcerative colitis** Indicated for the maintenance of remission of ulcerative colitis in adults.
Drug Name: Lialda (mesalamine 1.2g) delayed-release tablet
Treatment of mildly-moderately active ulcerative colitis Indicated for the induction of remission in adult patients with mildly to moderately active ulcerative colitis. Indicated for the treatment of mildly to moderately active ulcerative colitis in pediatric patients weighing at least 24 kg.

Maintenance of remission of ulcerative colitis Indicated for the maintenance of remission in adult patients with ulcerative colitis.

Drug Name: Apriso (mesalamine extended-release) capsules

Maintenance of remission of ulcerative colitis Indicated for the maintenance of remission in adult patients with ulcerative colitis.

Drug Name: Pentasa

Ulcerative colitis Indicated for the induction of remission and for the treatment of adult patients with mildly to moderately active ulcerative colitis.

2 . Criteria

Product Name:Asacol HD, Delzicol, Brand Lialda	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ASACOL HD	MESALAMINE TAB DELAYED RELEASE 800 MG	52500030000650	Brand
DELZICOL	MESALAMINE CAP DR 400 MG	52500030006530	Brand
LIALDA	MESALAMINE TAB DELAYED RELEASE 1.2 GM	52500030000670	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), age contraindication, or intolerance to brand Apriso [5]

Product Name:Pentasa	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
PENTASA	MESALAMINE CAP ER 500 MG	52500030000220	Brand
PENTASA	MESALAMINE CAP ER 250 MG	52500030000210	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to both of the following:

- Generic mesalamine (Delzicol, Asacol HD, Pentasa 500mg, Lialda)
- Brand Apriso

Product Name:Generic mesalamine ER capsules 0.375 gm (generic Apriso)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MESALAMINE ER	MESALAMINE CAP ER 24HR 0.375 GM	52500030007020	Generic

Approval Criteria

1 - One of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming at least 6 months use of brand Apriso within the previous 365 days

AND

3 - Justification provided for why the generic is expected to provide benefit when brand Apriso has not been shown to be effective

3 . References

1. Apriso Prescribing Information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. October 2023.
2. Asacol HD Prescribing Information. Allergan USA, Inc. Madison, NJ. November 2022.
3. Delzicol Prescribing Information. Allergan USA, Inc. Irvine, CA. October 2023.
4. Lialda Prescribing Information. Shire US Inc. Lexington, MA. October 2023.
5. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol, 2019;114:384–413.
6. Mesalamine delayed-release Prescribing Information. Zydus Pharmaceuticals, Inc. Pennington, NJ. October 2023.
7. Pentasa Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. October 2023.

Prior Authorization Guideline

Guideline ID	GL-228342
Guideline Name	5HT-1 Receptor Agonists (Triptans)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Onzetra Xsail (sumatriptan)
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Onzetra Xsail, reconsider the diagnosis of migraine before treatment of subsequent attacks with Onzetra Xsail. Onzetra Xsail is not indicated for the prevention of migraine attacks. Safety and effectiveness of Onzetra Xsail have not been established for the treatment of cluster headache.
Drug Name: Tosymra (sumatriptan)
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Tosymra, reconsider the diagnosis before Tosymra is administered to treat any subsequent attacks. Tosymra is not indicated for the preventive treatment of migraine. Tosymra is not indicated for the treatment of cluster headache.
Drug Name: Treximet (sumatriptan/naproxen)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.
Drug Name: Zomig (zolmitriptan) nasal spray
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.
Drug Name: Zembrace SymTouch (sumatriptan) injection solution
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Zembrace SymTouch, reconsider the diagnosis before Zembrace SymTouch is administered to treat any subsequent attacks. Zembrace SymTouch injection is not indicated for the prevention of migraine attacks.

2 . Criteria

Product Name:Onzetra Xsail, Brand Treximet, Generic sumatriptan/naproxen, Tosymra, or Zembrace SymTouch	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TREXIMET	SUMATRIPTAN-NAPROXEN SODIUM TAB 85-500 MG	67992002600320	Brand
TREXIMET	SUMATRIPTAN-NAPROXEN SODIUM TAB 10-60 MG	67992002600305	Brand
ONZETRA XSAIL	SUMATRIPTAN SUCCINATE EXHALER POWDER 11 MG/NOSEPIECE	6740607010G420	Brand
TOSYMRA	SUMATRIPTAN NASAL SPRAY 10 MG/ACT	67406070002020	Brand

SUMATRIPTAN/NAPROXEN SODIUM	SUMATRIPTAN-NAPROXEN SODIUM TAB 85-500 MG	67992002600320	Generic
ZEMBRACE SYMTOUCH	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 3 MG/0.5ML	6740607010D505	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) or intolerance to two of the following generics [A, B]:

- Almotriptan tablet
- Eletriptan tablet
- Frovatriptan tablet
- Naratriptan tablet
- Rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)
- Sumatriptan tablet/nasal spray
- Zolmitriptan tablet/zolmitriptan ODT

Product Name:Zomig nasal spray or Brand Zolmitriptan nasal spray	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ZOMIG	ZOLMITRIPTAN NASAL SPRAY 2.5 MG/SPRAY UNIT	67406080002010	Brand
ZOMIG	ZOLMITRIPTAN NASAL SPRAY 5 MG/SPRAY UNIT	67406080002020	Brand
ZOLMITRIPTAN	ZOLMITRIPTAN NASAL SPRAY 2.5 MG/SPRAY UNIT	67406080002010	Generic
ZOLMITRIPTAN	ZOLMITRIPTAN NASAL SPRAY 5 MG/SPRAY UNIT	67406080002020	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is 12 to 17 years of age

AND

2.1.2 Trial and failure (of a minimum 30-day supply) or intolerance to rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)

OR

2.2 Both of the following:

2.2.1 Patient is 18 years of age or older

AND

2.2.2 Trial and failure (of a minimum 30-day supply) or intolerance to two of the following generics [A, B]:

- Almotriptan tablet
- Eletriptan tablet
- Frovatriptan tablet
- Naratriptan tablet
- Rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)
- Sumatriptan tablet/nasal spray
- Zolmitriptan tablet/zolmitriptan ODT

3 . Endnotes

A. All triptans are FDA-approved for the acute treatment of migraines with or without aura in adults [3]. Those agents FDA-approved in pediatric patients include almotriptan, sumatriptan/naproxen, zolmitriptan nasal spray (for ≥12 years of age), and rizatriptan (for ≥6 years of age).
B. Triptans are a well established, effective treatment option for acute migraine [4]. There is limited head-to-head data available, which makes it difficult to recommend the use of one agent over another [4].

4 . References

1. Treximet Prescribing Information. Currax Pharmaceuticals LLC. Brentwood, TN. January 2024.
2. Onzetra Xsail Prescribing Information. Currax Pharmaceuticals LLC. Morristown, NJ. December 2019.
3. Drugs@FDA [internet database]. Rockville (MD): Food and Drug Administration (US), Center for Drug Evaluation and Research; Updated periodically. Available from: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. Accessed January 23, 2024.
4. Schwedt TJ, Garza I. Acute treatment of migraine in adults. UpToDate. Available by subscription at: http://www.uptodate.com/. Accessed January 23, 2024.
5. Zomig Nasal Spray Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.
6. Tosymra Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN. February 2021.
7. Zembrace SymTouch Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN. February 2021.

Actimmune (interferon gamma-1b)

Prior Authorization Guideline

Guideline ID	GL-228779
Guideline Name	Actimmune (interferon gamma-1b)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Actimmune (interferon gamma-1b)
Chronic Granulomatous Disease (CGD) Indicated for reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD). **Severe Malignant Osteopetrosis (SMO)** Indicated for delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO).

2 . Criteria

Product Name:Actimmune	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTIMMUNE	INTERFERON GAMMA-1B INJ 100 MCG/0.5ML (2000000 UNIT/0.5ML)	21700060702020	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Chronic granulomatous disease (CGD)
- Severe, malignant osteopetrosis (SMO)

Product Name:Actimmune	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTIMMUNE	INTERFERON GAMMA-1B INJ 100 MCG/0.5ML (2000000 UNIT/0.5ML)	21700060702020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Background

Benefit/Coverage/Program Information
Effective date Prior to 3/8/2023 Updates the effective date was 1/1/2021

4 . References

1. Actimmune Prescribing Information. Horizon Therapeutics USA, Inc. Deerfield, IL. March 2021.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233365
Guideline Name	Adakveo (crizanlizumab-tmca)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	1/15/2020
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Adakveo (crizanlizumab-tmca)
Sickle Cell Disease Indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.

2 . Criteria

Product Name:Adakveo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADAKVEO	CRIZANLIZUMAB-TMCA IV SOLN 100 MG/10ML	82807020702020	Brand

Approval Criteria

1 - Diagnosis of Sickle Cell Disease

AND

2 - Patient is 16 years of age and older

AND

3 - Documentation of 2 vaso-occlusive events that required medical facility visits and treatments in the past 12 months (e.g., sickle cell crisis, acute pain episodes, acute chest syndrome, hepatic sequestration, splenic sequestration, priapism) [1, 2]

AND

4 - Trial and failure or inadequate response, contraindication, or intolerance to one of the following: [3, 4, 5, 6]

- Hydroxyurea
- L-glutamine (i.e., Endari)

AND

5 - Prescribed by or in consultation with one of the following:

- Hematologist/Oncologist
- Specialist with expertise in the diagnosis and management of sickle cell disease

Product Name:Adakveo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADAKVEO	CRIZANLIZUMAB-TMCA IV SOLN 100 MG/10ML	82807020702020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in annual rate of vaso-occlusive events, increased time between each vaso-occlusive event)

3 . References

1. Adakveo (crizanlizumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.
2. Ataga K, Kutlar A, Kanter J et al. Crizanlizumab for the Prevention of Pain Crises in Sickle Cell Disease. New England Journal of Medicine. 2017;376(5):429-439. doi:10.1056/nejmoa1611770.
3. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. Nhlbi.nih.gov. https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Published 2014. Accessed December 6, 2021.
4. Brawley O, Cornelius L, Edwards L et al. National Institutes of Health Consensus Development Conference Statement: Hydroxyurea Treatment for Sickle Cell Disease. Ann Intern Med. 2008;148(12):932. doi:10.7326/0003-4819-148-12-200806170-00220.
5. Niihara Y, Miller S, Kanter J et al. A Phase 3 Trial of l-Glutamine in Sickle Cell Disease. New England Journal of Medicine. 2018;379(3):226-235. doi:10.1056/nejmoa1715971.
6. Brandow A, Carroll C, Creary S et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Adv. 2020;4(12):2656-2701. doi:10.1182/bloodadvances.2020001851.

4 . Revision History

Date	Notes
3/6/2025	Quartz Com/EHB copied to mirrow OptumRx and EHB

Adalimumab*

Prior Authorization Guideline

Guideline ID	GL-229091
Guideline Name	Adalimumab*
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/6/2025

Note:

*Do not approve Cordavis manufacture.

1 . Indications

Drug Name: Humira (adalimumab)
Rheumatoid arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severe active rheumatoid arthritis (RA). Humira can be used alone or in combination with methotrexate (MTX) or other non-biologic disease-modifying antirheumatic drugs (DMARDs). **Polyarticular Juvenile idiopathic arthritis (PJIA)** Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 years of age and older. Humira can be used alone or in combination with MTX. **Psoriatic arthritis (PsA)** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Humira can be used alone or in combination with non-biologic DMARDs.

Plaque psoriasis (PsO) Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Humira should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Ankylosing spondylitis (AS) Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Crohn's disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. Limitations of use: The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to TNF blockers.

Hidradenitis Suppurativa (HS) Indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

Uveitis (UV) Indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adults and pediatric patients 2 years of age and older.

Drug Name: Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

Rheumatoid arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

Polyarticular Juvenile idiopathic arthritis (PJIA) Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Can be used alone or in combination with methotrexate.

Psoriatic arthritis (PsA) Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Can be used alone or in combination with non-biologic DMARDs.

Plaque psoriasis (PsO) Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Ankylosing spondylitis (AS) Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Crohn's disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adult patients. Limitations of use: The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF-blockers.

Hidradenitis Suppurativa (HS) Indicated for the treatment of moderate to severe hidradenitis suppurativa in adult patients.

Uveitis (UV) Indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

2 . Criteria

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand

HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand

HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand

HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Diagnosis of moderate to severely active PJIA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand

HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz* , Hadlima, Adalimumab-fkjp	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand

HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz* , Hadlima, Adalimumab-fkjp	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand

HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

• Reduction in the body surface area (BSA) involvement from baseline

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand

HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - One of the following [6]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [7]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)

- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz* , Hadlima, Adalimumab-fkjp	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand

HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1, 6]:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand

HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [8]

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand

HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand

ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 8]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Crohn’s disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand

HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn’s disease

AND

2 - One of the following [9, 10]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [9, 10]

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Crohn’s disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand

ULCERATIVE COLITIS STARTER PACK			
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 9, 10]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand

HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [11, 12]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [11, 12]

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand

HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - One of the following:

1.1 For patients who initiated Humira therapy within the past 12 weeks, patient demonstrates clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy

OR

1.2 For patients who have been maintained on Humira therapy for longer than 12 weeks, patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 11, 12]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand

HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

AND

2 - Prescribed by or in consultation with a dermatologist

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand

HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Uveitis (UV)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand

HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Diagnosis of non-infectious uveitis

AND

2 - Uveitis is classified as one of the following:

- intermediate
- posterior
- panuveitis

AND

3 - Prescribed by or in consultation with one of the following:

- ophthalmologist
- rheumatologist

Notes	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Hyrimoz, Brand Adalimumab-adaz*, Hadlima, Adalimumab-fkjp	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001504D515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001504D520	Brand
HYRIMOZ SENSOREADY PENS	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ CROHN'S DISEASE AND ULCERATIVE COLITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	Brand
HYRIMOZ PLAQUE PSORIASIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand
HYRIMOZ PLAQUE PSORIASIS/UVEITIS STARTER PACK	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML	6627001504D560	Brand

HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001504E515	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001504E520	Brand
HYRIMOZ PEDIATRIC CROHNS DISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 80 MG/0.8ML	6627001504E540	Brand
HYRIMOZ PEDIATRIC CROHN'SDISEASE STARTER PACK	ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML	6627001504E560	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Notes	Approve at GPI 8 with Ignore Drug Status of I.

3 . References

1. Humira Prescribing Information. Abbvie Inc. North Chicago, IL. February 2021.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.

3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
7. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
8. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
9. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
10. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.
11. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
12. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.
13. Amjevita Prescribing Information. Amgen Inc. Thousand Oaks, CA. August 2023.
14. Cyltezo Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.
15. Hyrimoz Prescribing Information. Sandoz Inc. Princeton, NJ. April 2024.

Adasuve (loxapine)

Prior Authorization Guideline

Guideline ID	GL-233322
Guideline Name	Adasuve (loxapine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/18/2025
P&T Approval Date:	4/8/2014
P&T Revision Date:	3/20/2024

1 . Indications

Drug Name: Adasuve (loxapine)
Agitation Indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults. Limitations of Use: As part of the Adasuve REMS Program to mitigate the risk of bronchospasm, Adasuve must be administered only in a certified healthcare setting.

2 . Criteria

Product Name:Adasuve	
Approval Length	1 Time [A]

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADASUVE	LOXAPINE AEROSOL POWDER BREATH ACTIVATED 10 MG	59154020008010	Brand

Approval Criteria

1 - One of the following diagnoses:

- Bipolar I disorder
- Schizophrenia

AND

2 - For the treatment of acute agitation

AND

3 - Patient does not have a history of lung disease associated with bronchospasm [e.g., asthma, chronic obstructive pulmonary disease (COPD)]

3 . Endnotes

A. Because clinical trials in patients with asthma or COPD demonstrated that the degree of bronchospasm, as indicated by changes in forced expiratory volume in 1 second (FEV1), was greater following a second dose of Adasuve, limit Adasuve use to a single dose within a 24 hour period.

4 . References

1. Adasuve Prescribing Information. Galen US, Inc.; Souderton, PA. January 2022.

5 . Revision History

Date	Notes
2/18/2025	Quartz Commercial copied to mirrow OptumRx

Adbry (tralokinumab-ldrm)

Prior Authorization Guideline

Guideline ID	GL-228757
Guideline Name	Adbry (tralokinumab-ldrm)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Adbry (tralokinumab-ldrm)
Atopic Dermatitis Indicated for the treatment of moderate-to-severe atopic dermatitis in adults and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. May be used with or without topical corticosteroids.

2 . Criteria

Product Name:Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	6 Months*
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADBRY	TRALOKINUMAB-LDRM SUBCUTANEOUS SOLN PREFILLED SYR 150 MG/ML	9027308045E520	Brand
ADBRY	TRALOKINUMAB-LDRM SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9027308045D530	Brand

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream^

• Tacrolimus ointment • Eucrisa (crisaborole) ointment^	
Notes	*QL Override (For new starts only): Enter 2 PAs as follows: First PA: Approve with MDD = 0.29 & PTD = 6 syringes or 4 autoinjectors per 28 days for one month; Second PA: Approve 4 syringes or 2 autoinjectors per 28 days (no overrides needed) for the remaining 5 months. (Adbry is hard-coded with a quantity of 4 syringes per 28 days); ^Product may require step therapy

Product Name:Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADBRY	TRALOKINUMAB-LDRM SUBCUTANEOUS SOLN PREFILLED SYR 150 MG/ML	9027308045E520	Brand
ADBRY	TRALOKINUMAB-LDRM SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9027308045D530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

3 . Background

Clinical Practice Guidelines
Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1

	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [3, 4] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [5]

5 . References

1. Adbry Prescribing Information. Leo Pharma Inc. Madison, NJ. June 2024.
2. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
3. European Task Force on Atopic Dermatitis. Severity scoring of atopic dermatitis: the SCORAD index. Consensus report of the European Task Force on atopic dermatitis. Dermatology. 1993; 186:23-31.

4. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. Lancet 2017; 389(10086)(suppl):2287-2303.
5. Oranje AP. Practical issues on interpretation of scoring atopic dermatitis: SCORAD index, objective SCORAD, patient-oriented SCORAD and three-item severity score. Curr Probl Dermatol. 2011; 41:149-55.

Prior Authorization Guideline

Guideline ID	GL-233312
Guideline Name	ADHD
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/13/2025
P&T Approval Date:	5/21/1999
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Adderall XR (amphetamine-dextroamphetamine mixed salts extended-release)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older.
Drug Name: Concerta (methylphenidate extended-release)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children 6 years of age and older, adolescents, and adults up to the age of 65.
Drug Name: Cotempla XR-ODT (methylphenidate extended-release)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

Drug Name: Daytrana (methylphenidate transdermal system)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.
Drug Name: Desoxyn (methamphetamine)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of attention deficit disorder with hyperactivity as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children over 6 years of age with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.
Drug Name: ProCentra (dextroamphetamine oral solution)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of attention deficit disorder with hyperactivity as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in pediatric patients (ages 3 to 16 years) with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. **Narcolepsy** Indicated for the treatment of narcolepsy.
Drug Name: Focalin (dexmethylphenidate)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD)
Drug Name: Focalin XR (dexmethylphenidate extended-release)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients aged 6 years and older.
Drug Name: Methylin (methylphenidate oral solution)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years of age and older. **Narcolepsy** Indicated for the treatment of narcolepsy.
Drug Name: Ritalin (methylphenidate)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in pediatric patients 6 years and older and adults. **Narcolepsy** Indicated for the treatment of narcolepsy.

Drug Name: Ritalin LA (methylphenidate extended-release)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of attention deficit hyperactivity disorder (ADHD), in pediatric patients 6 to 12 years of age.
Drug Name: Quillivant XR (methylphenidate extended-release oral suspension)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of attention deficit hyperactivity disorder (ADHD).
Drug Name: Aptensio XR (methylphenidate HCl extended-release)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older. Limitations of Use: Pediatric patients younger than 6 years of age experienced higher plasma exposure than patients 6 years and older at the same dose and high rates of adverse reactions, most notably weight loss.
Drug Name: Zenzedi (dextroamphetamine)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in pediatric patients (ages 3 to 16 years) with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. **Narcolepsy** Indicated for the treatment of narcolepsy.
Drug Name: Dyanavel XR (amphetamine extended-release)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older
Drug Name: Quillichew ER (methylphenidate extended-release, chewable)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD)
Drug Name: Adzenys XR-ODT (amphetamine extended-release, orally disintegrating tablet)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.
Drug Name: Mydayis (mixed amphetamine salts)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older. Limitation of use: Pediatric patients 12 years and younger experienced higher plasma exposure than patients

13 years and older at the same dose, and experienced higher rates of adverse reactions, mainly insomnia and decreased appetite.

Drug Name: Jornay PM (methylphenidate extended-release capsule)

Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

Drug Name: CNS Stimulants

Augmentation of Depression [21-23] Have been used in the treatment of depression as part of an augmentation strategy in patients who are refractory to standard antidepressant therapy.

Drug Name: Azstarys (serdexmethylphenidate and dexmethylphenidate)

Attention Deficit Hyperactivity Disorder (ADHD) AZSTARYS is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older.

Drug Name: Dexedrine (dextroamphetamine sulfate)

Narcolepsy Indicated for the treatment of narcolepsy.

Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years to 16 years.

Drug Name: Relexxi, Brand Methylphenidate ER

Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults (up to the age of 65 years) and pediatric patients 6 years of age and older.

Drug Name: Xelstrym (dextroamphetamine) transdermal system

Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older. Limitations of Use: Pediatric patients with ADHD younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.

Drug Name: Evekeo ODT (amphetamine sulfate) orally disintegrating tablets

Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

Drug Name: Evekeo (amphetamine sulfate)

Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of attention deficit disorder with hyperactivity as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing

effect in children with behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability , and impulsivity. **Narcolepsy** Indicated for the treatment of narcolepsy. **Exogenous Obesity** Indicated as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction for patients refractory to alternative therapy, e.g., repeated diets, group programs, and other drugs.
Drug Name: Vyvanse (lisdexamfetamine dimesylate) capsules, Vyvanse (lisdexamfetamine dimesylate) chewable tablets
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older. Limitation of Use: Vyvanse is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Vyvanse for the treatment of obesity have not been established. **Binge Eating Disorder (BED)** Indicated for the treatment of moderate to severe binge eating disorder (BED) in adults. Limitation of Use: Vyvanse is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Vyvanse for the treatment of obesity have not been established.
Drug Name: Metadate CD (methylphenidate hydrochloride)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 15 years of age.
Drug Name: Adderall (amphetamine-dextroamphetamine mixed salts)
Attention Deficit Hyperactivity Disorder (ADHD) Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). **Narcolepsy** Indicated for the treatment of Narcolepsy.

2 . Criteria

Product Name:Azstarys, Jornay PM	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
JORNAY PM	METHYLPHENIDATE HCL CAP DELAYED ER 24HR 20 MG (PM)	61400020107067	Brand
JORNAY PM	METHYLPHENIDATE HCL CAP DELAYED ER 24HR 40 MG (PM)	61400020107077	Brand
JORNAY PM	METHYLPHENIDATE HCL CAP DELAYED ER 24HR 60 MG (PM)	61400020107087	Brand
JORNAY PM	METHYLPHENIDATE HCL CAP DELAYED ER 24HR 80 MG (PM)	61400020107090	Brand
JORNAY PM	METHYLPHENIDATE HCL CAP DELAYED ER 24HR 100 MG (PM)	61400020107094	Brand
AZSTARYS	SERDEXMETHYLPHENIDATE-DEXMETHYLPHENIDATE CAP 26.1-5.2 MG	61409802800120	Brand
AZSTARYS	SERDEXMETHYLPHENIDATE-DEXMETHYLPHENIDATE CAP 39.2-7.8 MG	61409802800130	Brand
AZSTARYS	SERDEXMETHYLPHENIDATE-DEXMETHYLPHENIDATE CAP 52.3-10.4 MG	61409802800140	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance to one of the following [8-14]:*

- amphetamine-dextroamphetamine
- dexmethylphenidate
- dextroamphetamine
- methylphenidate
- lisdexamfetamine

Notes	*Intent is to accept immediate release and/or extended release generic preparation of the listed prerequisites when available

Product Name:Adzenys XR-ODT, Aptensio XR, Brand Adderall, Brand Metadate CD, Brand Methylphenidate XR, Brand Methylphenidate ER, Cotempla XR-ODT, Daytrana, Evekeo, Evekeo ODT, Brand Desoxyn, Brand Dexedrine, Dyanavel XR, Brand Focalin, Brand Focalin

XR, Brand Methylin oral solution, Brand Mydayis, Brand ProCentra, Quillichew ER, Quillivant XR, Brand Relexxii, Brand Ritalin, Brand Ritalin LA, Brand Zenzedi, Xelstrym	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
DAYTRANA	METHYLPHENIDATE TD PATCH 10 MG/9HR	61400020005910	Brand
DAYTRANA	METHYLPHENIDATE TD PATCH 15 MG/9HR	61400020005915	Brand
DAYTRANA	METHYLPHENIDATE TD PATCH 20 MG/9HR	61400020005920	Brand
DAYTRANA	METHYLPHENIDATE TD PATCH 30 MG/9HR	61400020005930	Brand
DESOXYN	METHAMPHETAMINE HCL TAB 5 MG	61100030100305	Brand
PROCENTRA	DEXTROAMPHETAMINE SULFATE ORAL SOLUTION 5 MG/5ML	61100020102020	Brand
FOCALIN XR	DEXMETHYLPHENIDATE HCL CAP SR 24 HR 5 MG	61400016107020	Brand
FOCALIN XR	DEXMETHYLPHENIDATE HCL CAP SR 24 HR 10 MG	61400016107030	Brand
FOCALIN XR	DEXMETHYLPHENIDATE HCL CAP SR 24 HR 15 MG	61400016107035	Brand
FOCALIN XR	DEXMETHYLPHENIDATE HCL CAP SR 24 HR 20 MG	61400016107040	Brand
FOCALIN XR	DEXMETHYLPHENIDATE HCL CAP SR 24 HR 25 MG	61400016107045	Brand
FOCALIN XR	DEXMETHYLPHENIDATE HCL CAP SR 24 HR 30 MG	61400016107050	Brand
FOCALIN XR	DEXMETHYLPHENIDATE HCL CAP SR 24 HR 35 MG	61400016107055	Brand
FOCALIN XR	DEXMETHYLPHENIDATE HCL CAP SR 24 HR 40 MG	61400016107060	Brand
METHYLIN	METHYLPHENIDATE HCL SOLN 5 MG/5ML	61400020102020	Brand
METHYLIN	METHYLPHENIDATE HCL SOLN 10 MG/5ML	61400020102030	Brand
RITALIN LA	METHYLPHENIDATE HCL CAP SR 24HR 10 MG	61400020107010	Brand
RITALIN LA	METHYLPHENIDATE HCL CAP SR 24HR 20 MG	61400020107020	Brand
RITALIN LA	METHYLPHENIDATE HCL CAP SR 24HR 30 MG	61400020107030	Brand
RITALIN LA	METHYLPHENIDATE HCL CAP SR 24HR 40 MG	61400020107040	Brand
APTENSIO XR	METHYLPHENIDATE HCL CAP ER 24HR 10 MG (XR)	61400020107055	Brand

APTENSIO XR	METHYLPHENIDATE HCL CAP ER 24HR 15 MG (XR)	61400020107060	Brand
APTENSIO XR	METHYLPHENIDATE HCL CAP ER 24HR 20 MG (XR)	61400020107065	Brand
APTENSIO XR	METHYLPHENIDATE HCL CAP ER 24HR 30 MG (XR)	61400020107070	Brand
APTENSIO XR	METHYLPHENIDATE HCL CAP ER 24HR 40 MG (XR)	61400020107075	Brand
APTENSIO XR	METHYLPHENIDATE HCL CAP ER 24HR 50 MG (XR)	61400020107080	Brand
APTENSIO XR	METHYLPHENIDATE HCL CAP ER 24HR 60 MG (XR)	61400020107085	Brand
ZENZEDI	DEXTROAMPHETAMINE SULFATE TAB 2.5 MG	61100020100303	Brand
ZENZEDI	DEXTROAMPHETAMINE SULFATE TAB 5 MG	61100020100305	Brand
ZENZEDI	DEXTROAMPHETAMINE SULFATE TAB 7.5 MG	61100020100308	Brand
ZENZEDI	DEXTROAMPHETAMINE SULFATE TAB 10 MG	61100020100310	Brand
ZENZEDI	DEXTROAMPHETAMINE SULFATE TAB 15 MG	61100020100315	Brand
ZENZEDI	DEXTROAMPHETAMINE SULFATE TAB 20 MG	61100020100330	Brand
ZENZEDI	DEXTROAMPHETAMINE SULFATE TAB 30 MG	61100020100350	Brand
DYANAVEL XR	AMPHETAMINE SUSP EXTENDED RELEASE 2.5 MG/ML	6110001000G120	Brand
ADZENYS XR-ODT	AMPHETAMINE TAB EXTENDED RELEASE DISPERSIBLE 3.1 MG	6110001000H410	Brand
ADZENYS XR-ODT	AMPHETAMINE TAB EXTENDED RELEASE DISPERSIBLE 6.3 MG	6110001000H420	Brand
ADZENYS XR-ODT	AMPHETAMINE TAB EXTENDED RELEASE DISPERSIBLE 9.4 MG	6110001000H430	Brand
ADZENYS XR-ODT	AMPHETAMINE TAB EXTENDED RELEASE DISPERSIBLE 12.5 MG	6110001000H440	Brand
ADZENYS XR-ODT	AMPHETAMINE TAB EXTENDED RELEASE DISPERSIBLE 15.7 MG	6110001000H450	Brand
ADZENYS XR-ODT	AMPHETAMINE TAB EXTENDED RELEASE DISPERSIBLE 18.8 MG	6110001000H460	Brand
QUILLICHEW ER	METHYLPHENIDATE HCL CHEW TAB EXTENDED RELEASE 20 MG	6140002010H220	Brand
QUILLICHEW ER	METHYLPHENIDATE HCL CHEW TAB EXTENDED RELEASE 30 MG	6140002010H230	Brand
QUILLICHEW ER	METHYLPHENIDATE HCL CHEW TAB EXTENDED RELEASE 40 MG	6140002010H240	Brand

MYDAYIS	AMPHETAMINE-DEXTROAMPHETAMINE 3-BEAD CAP ER 24HR 12.5 MG	61109902107060	Brand
MYDAYIS	AMPHETAMINE-DEXTROAMPHETAMINE 3-BEAD CAP ER 24HR 25 MG	61109902107065	Brand
MYDAYIS	AMPHETAMINE-DEXTROAMPHETAMINE 3-BEAD CAP ER 24HR 37.5 MG	61109902107070	Brand
MYDAYIS	AMPHETAMINE-DEXTROAMPHETAMINE 3-BEAD CAP ER 24HR 50 MG	61109902107075	Brand
COTEMPLA XR-ODT	METHYLPHENIDATE TAB EXTENDED RELEASE DISINTEGRATING 8.6 MG	6140002000H410	Brand
COTEMPLA XR-ODT	METHYLPHENIDATE TAB EXTENDED RELEASE DISINTEGRATING 17.3 MG	6140002000H420	Brand
COTEMPLA XR-ODT	METHYLPHENIDATE TAB EXTENDED RELEASE DISINTEGRATING 25.9 MG	6140002000H430	Brand
FOCALIN	DEXMETHYLPHENIDATE HCL TAB 2.5 MG	61400016100320	Brand
FOCALIN	DEXMETHYLPHENIDATE HCL TAB 5 MG	61400016100330	Brand
FOCALIN	DEXMETHYLPHENIDATE HCL TAB 10 MG	61400016100340	Brand
RITALIN	METHYLPHENIDATE HCL TAB 5 MG	61400020100305	Brand
RITALIN	METHYLPHENIDATE HCL TAB 10 MG	61400020100310	Brand
RITALIN	METHYLPHENIDATE HCL TAB 20 MG	61400020100315	Brand
QUILLIVANT XR	METHYLPHENIDATE HCL FOR ER SUSP 25 MG/5ML (5 MG/ML)	6140002010G220	Brand
DEXEDRINE	DEXTROAMPHETAMINE SULFATE CAP ER 24HR 5 MG	61100020107005	Brand
DEXEDRINE	DEXTROAMPHETAMINE SULFATE CAP ER 24HR 10 MG	61100020107010	Brand
DEXEDRINE	DEXTROAMPHETAMINE SULFATE CAP ER 24HR 15 MG	61100020107015	Brand
DYANAVEL XR	AMPHETAMINE CHEW TAB EXTENDED RELEASE 5 MG	61100010000410	Brand
DYANAVEL XR	AMPHETAMINE CHEW TAB EXTENDED RELEASE 10 MG	61100010000420	Brand
DYANAVEL XR	AMPHETAMINE CHEW TAB EXTENDED RELEASE 15 MG	61100010000430	Brand
DYANAVEL XR	AMPHETAMINE CHEW TAB EXTENDED RELEASE 20 MG	61100010000440	Brand
RELEXXII	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 72 MG	61400020100490	Generic
METHYLPHENIDATE HYDROCHLORIDE ER	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 45 MG	61400020100475	Generic
METHYLPHENIDATE HYDROCHLORIDE ER	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 63 MG	61400020100485	Generic

XELSTRYM	DEXTROAMPHETAMINE TD PATCH 4.5 MG/9HR	61100020005910	Brand
XELSTRYM	DEXTROAMPHETAMINE TD PATCH 9 MG/9HR	61100020005920	Brand
XELSTRYM	DEXTROAMPHETAMINE TD PATCH 13.5 MG/9HR	61100020005930	Brand
XELSTRYM	DEXTROAMPHETAMINE TD PATCH 18 MG/9HR	61100020005940	Brand
RELEXXII	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 45 MG	61400020100475	Generic
RELEXXII	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 63 MG	61400020100485	Generic
EVEKEO	AMPHETAMINE SULFATE TAB 5 MG	61100010100310	Brand
EVEKEO	AMPHETAMINE SULFATE TAB 10 MG	61100010100320	Brand
EVEKEO ODT	AMPHETAMINE SULFATE ORALLY DISINTEGRATING TAB 5 MG	61100010107210	Brand
EVEKEO ODT	AMPHETAMINE SULFATE ORALLY DISINTEGRATING TAB 10 MG	61100010107220	Brand
EVEKEO ODT	AMPHETAMINE SULFATE ORALLY DISINTEGRATING TAB 15 MG	61100010107230	Brand
EVEKEO ODT	AMPHETAMINE SULFATE ORALLY DISINTEGRATING TAB 20 MG	61100010107240	Brand
METHYLPHENIDATE HYDROCHLORIDE ER	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 72 MG	61400020100490	Generic
RELEXXII	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 18 MG	61400020100460	Brand
RELEXXII	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 27 MG	61400020100465	Brand
RELEXXII	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 36 MG	61400020100470	Brand
RELEXXII	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 54 MG	61400020100480	Brand
RELEXXII	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 72 MG	61400020100490	Brand
METADATE CD	METHYLPHENIDATE HCL CAP ER 10 MG (CD)	61400020100210	Brand
METADATE CD	METHYLPHENIDATE HCL CAP ER 20 MG (CD)	61400020100220	Brand
METADATE CD	METHYLPHENIDATE HCL CAP ER 30 MG (CD)	61400020100230	Brand
METADATE CD	METHYLPHENIDATE HCL CAP ER 40 MG (CD)	61400020100240	Brand
METADATE CD	METHYLPHENIDATE HCL CAP ER 50 MG (CD)	61400020100250	Brand

METADATE CD	METHYLPHENIDATE HCL CAP ER 60 MG (CD)	61400020100260	Brand
ADDERALL	AMPHETAMINE-DEXTROAMPHETAMINE TAB 5 MG	61109902100305	Brand
ADDERALL	AMPHETAMINE-DEXTROAMPHETAMINE TAB 7.5 MG	61109902100307	Brand
ADDERALL	AMPHETAMINE-DEXTROAMPHETAMINE TAB 10 MG	61109902100310	Brand
ADDERALL	AMPHETAMINE-DEXTROAMPHETAMINE TAB 12.5 MG	61109902100312	Brand
ADDERALL	AMPHETAMINE-DEXTROAMPHETAMINE TAB 15 MG	61109902100315	Brand
ADDERALL	AMPHETAMINE-DEXTROAMPHETAMINE TAB 20 MG	61109902100320	Brand
ADDERALL	AMPHETAMINE-DEXTROAMPHETAMINE TAB 30 MG	61109902100330	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance to three of the following [8-14]:*

- amphetamine-dextroamphetamine
- dexmethylphenidate
- dextroamphetamine
- methylphenidate
- lisdexamfetamine

Notes	*Intent is to accept immediate release and/or extended release generic preparation of the listed prerequisites when available

Product Name:Brand Concerta, Brand Adderall XR, Brand Vyvanse	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
CONCERTA	METHYLPHENIDATE HCL TAB SA OSM 18 MG	61400020100460	Brand
CONCERTA	METHYLPHENIDATE HCL TAB SA OSM 27 MG	61400020100465	Brand
CONCERTA	METHYLPHENIDATE HCL TAB SA OSM 36 MG	61400020100470	Brand
CONCERTA	METHYLPHENIDATE HCL TAB SA OSM 54 MG	61400020100480	Brand
CONCERTA	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 18 MG	61400020100460	Brand
CONCERTA	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 27 MG	61400020100465	Brand
CONCERTA	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 36 MG	61400020100470	Brand
CONCERTA	METHYLPHENIDATE HCL TAB ER OSMOTIC RELEASE (OSM) 54 MG	61400020100480	Brand
ADDERALL XR	AMPHETAMINE-DEXTROAMPHETAMINE CAP ER 24HR 5 MG	61109902107005	Brand
ADDERALL XR	AMPHETAMINE-DEXTROAMPHETAMINE CAP ER 24HR 10 MG	61109902107010	Brand
ADDERALL XR	AMPHETAMINE-DEXTROAMPHETAMINE CAP ER 24HR 15 MG	61109902107015	Brand
ADDERALL XR	AMPHETAMINE-DEXTROAMPHETAMINE CAP ER 24HR 20 MG	61109902107020	Brand
ADDERALL XR	AMPHETAMINE-DEXTROAMPHETAMINE CAP ER 24HR 25 MG	61109902107025	Brand
ADDERALL XR	AMPHETAMINE-DEXTROAMPHETAMINE CAP ER 24HR 30 MG	61109902107030	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CAP 10 MG	61100025100110	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CAP 20 MG	61100025100120	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CAP 30 MG	61100025100130	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CAP 40 MG	61100025100140	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CAP 50 MG	61100025100150	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CAP 60 MG	61100025100160	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CAP 70 MG	61100025100170	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CHEW TAB 10 MG	61100025100510	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CHEW TAB 20 MG	61100025100520	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CHEW TAB 30 MG	61100025100530	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CHEW TAB 40 MG	61100025100540	Brand
VYVANSE	LISDEXAMFETAMINE DIMESYLATE CHEW TAB 50 MG	61100025100550	Brand

VYVANSE	LISDEXAMFETAMINE DIMESYLATE CHEW TAB 60 MG	61100025100560	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30-day supply), contraindication or intolerance to three of the following [8-14]:*

- amphetamine-dextroamphetamine
- dexmethylphenidate
- dextroamphetamine
- methylphenidate
- lisdexamfetamine

OR

2 - For continuation of prior therapy if a minimum 30-day supply was used within the past 120 days

Notes	*Intent is to accept immediate release and/or extended release generic preparation of the listed prerequisites when available

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4 . Revision History

Date	Notes
1/13/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-229111
Guideline Name	Administrative Non-Formulary & Excluded Drug Exceptions Process
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/21/2024

Note:

The purpose of this guideline is to establish policies and procedures on how to handle non-formulary and excluded drugs. This guideline will not apply to drugs with step therapy edits, drugs that require quantity limit review only, or drugs that are not reviewed for prior authorization by OptumRx. ** Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity **

1 . Criteria

Product Name:A non-formulary or excluded* contraceptive drug	
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
contraceptive			
contraception			
contraceptives			

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Patient is using the requested product for contraception or other FDA-approved condition**
- The requested product is medically necessary***

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Notes	*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity. **Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmenorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner's syndrome; (17) Uterine fibroids or adenomyosis. ***Any justification of medical necessity/appropriateness provided by the prescriber is adequate to approve access.

Product Name:A non-formulary or excluded* drug	
Approval Length	6 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

Non-formulary drug			
Excluded drug			
Exclusion			
non			
non-form			
non-formulary			

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 If the requested drug has a formulary alternative with the same active ingredient, both of the following:

1.1.1.1 Submission of medical records (e.g., chart notes) documenting the patient has experienced intolerance (e.g., allergy to excipient) with a formulary alternative that has the same active ingredient

AND

1.1.1.2 Submission of medical records (e.g., chart notes) or paid claims documenting the patient has tried and failed at least 2 additional formulary alternatives within the same therapeutic class. If only 1 formulary alternative within the therapeutic class is available, the patient must have tried the formulary alternative within the therapeutic class AND 1 additional formulary alternative. If there are no formulary alternatives within the same therapeutic class, the patient must have failed 2 formulary alternatives or have a contraindication or intolerance to all formulary alternatives.

OR

1.1.2 If the requested drug is a fixed-dose combination product with each individual ingredients available on formulary, both of the following:

1.1.2.1 Submission of medical records (e.g., chart notes) documenting the patient has experienced intolerance (e.g., allergy to excipient) with the individual ingredients in the combination product

AND

1.1.2.2 Submission of medical records (e.g., chart notes) or paid claims documenting the patient has tried and failed at least 2 additional formulary alternatives

OR

1.1.3 If only over-the-counter (OTC) equivalents^ are available, patient has tried and failed or has contraindications or intolerance to 3 OTC equivalents. If only 1 or only 2 equivalents are available, the patient must have failed or has contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial]

OR

1.1.4 If formulary alternatives are available and do not meet above scenarios, submission of medical records (e.g., chart notes) or paid claims documenting patient has tried and failed at least 3 formulary alternatives or has contraindications or intolerance to all formulary alternatives. If only 1 or only 2 alternatives are available, the patient must have failed or has contraindications or intolerance to all available formulary alternatives.

OR

1.1.5 No formulary alternative or OTC equivalent is available to treat the patient's condition

AND

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2.1.2 Additional requirements listed in the "Indications and Usage" sections of the

prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.) **OR** **1.2.2** If requested for an off-label indication, the off-label guideline approval criteria have been met	
Notes	*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity. *If the target drug is listed on the ORx Commercial grid, the patient must try and fail, or have specific medical reason(s) for why the number of alternatives specified by the grid is not appropriate. ^OTC equivalent refers to any covered or non-covered OTC equivalent product. If the diagnosis provided for the target drug is FDA approved/compendia supported, then consider the OTC equivalent(s) to have the same FDA approval/compendia support.

2 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228764
Guideline Name	Adzynma (ADAMTS13, recombinant-krhn)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Adzynma (ADAMTS13, recombinant-krhn)
Congenital Thrombotic Thrombocytopenic Purpura (cTTP) Indicated for prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP).

2 . Criteria

Product Name:Adzynma	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADZYNMA	ADAMTS13 RECOMBINANT-KRHN FOR INJ KIT 500 UNIT	85182005306420	Brand
ADZYNMA	ADAMTS13 RECOMBINANT-KRHN FOR INJ KIT 1500 UNIT	85182005306440	Brand

Approval Criteria

1 - Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP)

AND

2 - Molecular genetic testing confirms mutations in the ADAMTS13 gene

AND

3 - Trial and inadequate response, contraindication or intolerance to plasma-based infusions [B, 11]

Product Name:Adzynma	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADZYNMA	ADAMTS13 RECOMBINANT-KRHN FOR INJ KIT 500 UNIT	85182005306420	Brand
ADZYNMA	ADAMTS13 RECOMBINANT-KRHN FOR INJ KIT 1500 UNIT	85182005306440	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and inadequate response, contraindication or intolerance to plasma-based infusions [B, 11]

3 . Definitions

Definition	Description
ISTH	International Society of Thrombosis and Haemostasis.

4 . Endnotes

A. Acute TTP events were defined in protocol by a drop in platelet count (≥50% of baseline or a platelet count <100,000/μL) and an elevation of lactate dehydrogenase (LDH) (>2× baseline or >2× upper limit normal (ULN)). Subacute events were defined by a thrombocytopenia event or a microangiopathic hemolytic anemia event; and organ-specific signs and symptoms including but not limited to renal dysfunction events, neurological symptoms events, fever, fatigue/lethargy, and/or abdominal pain. Thrombocytopenia events were defined as a drop in platelet count ≥25% of baseline or a platelet count <150,000/μL. Microangiopathic hemolytic anemia events were defined as an elevation of LDH >1.5×baseline or >1.5 ×ULN. [2]

B. A trial of plasma-based infusions would be acceptable for both prophylactic and acute use in cTTP. Adzynma may be an option for those patients who have risk of antibody production, allergic reactions, time-constraints (few hours with plasma-based infusions), refractory to plasma-based infusions, volume restrictions (e.g., renal failure) etc... [11]

5 . References

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Aemcolo (rifamycin)

Prior Authorization Guideline

Guideline ID	GL-228761
Guideline Name	Aemcolo (rifamycin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Aemcolo (rifamycin)
Travelers' Diarrhea (TD) Indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adults. Limitations of use: Aemcolo is not indicated in patients with diarrhea complicated by fever or bloody stool or due to pathogens other than noninvasive strains of Escherichia coli. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Aemcolo and other antibacterial drugs, Aemcolo should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

2 . Criteria

Product Name:Aemcolo	
Approval Length	14 days [A]

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AEMCOLO	RIFAMYCIN SODIUM TAB DELAYED RELEASE 194 MG (BASE EQUIV)	16000048200620	Brand

Approval Criteria

1 - Diagnosis of travelers' diarrhea (TD) [B]

AND

2 - Diarrhea is not accompanied by fever or bloody stool [B]

AND

3 - One of the following:

3.1 Trial and failure to one of the following: [2, C]

- Zithromax (azithromycin)
- Cipro (ciprofloxacin)
- Levaquin (levofloxacin)
- Ofloxacin

OR

3.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

- Zithromax (azithromycin)
- Cipro (ciprofloxacin)
- Levaquin (levofloxacin)
- Ofloxacin

3 . Endnotes

A. The recommended dosage of Aemcolo is 388 mg (two tablets) orally twice daily for three days. 14 day approval length allows for sufficient time for the patient to pick up the medication from the pharmacy. [1]
B. For those who present with uncomplicated travelers' diarrhea (TD), determination of the microbiologic agent is generally unnecessary, but when culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. Aemcolo was not shown to be effective in patients with diarrhea complicated by fever and/or bloody stool. The effectiveness of Aemcolo in TD caused by pathogens other than E. coli has not been demonstrated. [1, 2]
C. According to the Centers for Disease Control and Prevention's Yellow Book, fluoroquinolones including, but not limited to, ciprofloxacin and levofloxacin, are considered first line agents in the treatment of TD. Azithromycin is also considered a first line agent for treatment of TD and is especially efficacious in the pediatric population. [2, 3]

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Prior Authorization Guideline

Guideline ID	GL-228784
Guideline Name	Afinitor, Afinitor Disperz (everolimus) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Afinitor (everolimus tablet)
Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET) Indicated for the treatment of progressive PNET in adult patients with unresectable, locally advanced or metastatic disease. Afinitor is not indicated for the treatment of patients with functional carcinoid tumors. **Advanced Renal Cell Carcinoma (RCC)** Indicated for the treatment of adult patients with advanced RCC after failure of treatment with sunitinib or sorafenib. **Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)** Indicated for the treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery. **Subependymal Giant Cell Astrocytoma (SEGA)** Indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. **Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR + BC)** Indicated for the treatment of postmenopausal women with advanced hormone receptor-

positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole.

Neuroendocrine Tumors of Gastrointestinal or Lung Origin Indicated for the treatment of adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors.

Drug Name: Torpenz (everolimus tablet)

Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC) Indicated for the treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery.

Subependymal Giant Cell Astrocytoma (SEGA) Indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.

Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR + BC) Indicated for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole.

Drug Name: Afinitor Disperz (everolimus tablet for oral suspension)

Subependymal Giant Cell Astrocytoma (SEGA) Indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. The effectiveness of Afinitor Disperz is based on demonstration of durable objective response, as evidenced by reduction in SEGA tumor volume. Improvement in disease-related symptoms and overall survival in patients with SEGA and TSC has not been demonstrated.

Tuberous Sclerosis Complex (TSC) Associated Partial-onset Seizures Indicated for the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures

2 . Criteria

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz (off-label)	
Diagnosis	Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Diagnosis of progressive neuroendocrine tumors of pancreatic origin

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz (off-label)	
Diagnosis	Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Product Name:Brand Afinitor	
Diagnosis	Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of progressive neuroendocrine tumors of pancreatic origin

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to generic everolimus tablet

AND

4 - Submission of medical records confirming the formulary alternative(s) has not been effective AND justification/rationale provided explaining how Brand Afinitor is expected to provide benefit when the formulary alternative has not been shown to be effective despite having the same active ingredient

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz (off-label)	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - Trial and failure with one of the following*:

- Sutent (sunitinib)
- Nexavar (sorafenib)

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Notes	*Criterion is part of the FDA-approved label.

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz (off-label)	
Diagnosis	Advanced Renal Cell Carcinoma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Product Name:Brand Afinitor	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of advanced renal cell carcinoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure with one of the following*:

- Sutent (sunitinib)
- Nexavar (sorafenib)

AND

3 - Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to generic everolimus tablet

AND

4 - Submission of medical records confirming the formulary alternative(s) has not been effective AND justification/rationale provided explaining how Brand Afinitor is expected to provide benefit when the formulary alternative has not been shown to be effective despite having the same active ingredient

Notes	*Criterion is part of the FDA-approved label.

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC)

AND

2 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

3 - Prescribed by or in consultation with a nephrologist

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Product Name:Brand Afinitor	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand

AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC)

AND

2 - Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to generic everolimus tablet

AND

3 - Submission of medical records confirming the formulary alternative(s) has not been effective AND justification/rationale provided explaining how Brand Afinitor is expected to provide benefit when the formulary alternative has not been shown to be effective despite having the same active ingredient

AND

4 - Prescribed by or in consultation with a nephrologist

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz, Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	Subependymal Giant Cell Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand

AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 2 MG	21532530007310	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 3 MG	21532530007320	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 2 MG	21532530007310	Generic
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 3 MG	21532530007320	Generic
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

AND

2 - Patient is 1 year of age or older

AND

3 - One of the following:

3.1 Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

OR

3.2 Trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz, Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	Subependymal Giant Cell Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 2 MG	21532530007310	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 3 MG	21532530007320	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 2 MG	21532530007310	Generic
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 3 MG	21532530007320	Generic
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic

TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

OR

2.2 Trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

Product Name:Brand Afinitor, Brand Afinitor Disperz	
Diagnosis	Subependymal Giant Cell Astrocytoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 2 MG	21532530007310	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 3 MG	21532530007320	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

AND

2 - Patient is 1 year of age or older

AND

3 - One of the following:

3.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to generic everolimus tablet (applies to Brand Afinitor only)

OR

3.2 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

AND

4 - Submission of medical records confirming the formulary alternative(s) has not been effective AND justification/rationale provided explaining how Brand Afinitor or Brand Afinitor Disperz is expected to provide benefit when the formulary alternative has not been shown to be effective despite having the same active ingredient

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Diagnosis of hormone receptor positive, HER-2 negative advanced breast cancer

AND

2 - Trial and failure, contraindication, or intolerance to one of the following*:

- Femara (letrozole)
- Arimidex (anastrozole)

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Notes	*Criterion is part of the FDA-approved label.

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz

Diagnosis	Breast cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Product Name:Brand Afinitor	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of hormone receptor positive, HER-2 negative advanced breast cancer

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following*:

- Femara (letrozole)
- Arimidex (anastrozole)

AND

3 - Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to generic everolimus tablet

AND

4 - Submission of medical records confirming the formulary alternative(s) has not been effective AND justification/rationale provided explaining how Brand Afinitor is expected to provide benefit when the formulary alternative has not been shown to be effective despite having the same active ingredient

Notes	*Criterion is part of the FDA-approved label.

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz (off-label)	
Diagnosis	Neuroendocrine tumors of gastrointestinal or lung origin

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung origin

AND

2 - One of the following:

- Unresectable, locally advanced disease
- Metastatic disease

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Product Name:Brand Afinitor, Generic everolimus tablet, Torpenz (off-label)	
Diagnosis	Neuroendocrine tumors of gastrointestinal or lung origin
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
EVEROLIMUS	EVEROLIMUS TAB 5 MG	21532530000320	Generic
EVEROLIMUS	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
EVEROLIMUS	EVEROLIMUS TAB 10 MG	21532530000330	Generic
TORPENZ	EVEROLIMUS TAB 2.5 MG	21532530000310	Generic
TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Product Name:Brand Afinitor	
Diagnosis	Neuroendocrine tumors of gastrointestinal or lung origin
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR	EVEROLIMUS TAB 2.5 MG	21532530000310	Brand
AFINITOR	EVEROLIMUS TAB 5 MG	21532530000320	Brand
AFINITOR	EVEROLIMUS TAB 7.5 MG	21532530000325	Brand
AFINITOR	EVEROLIMUS TAB 10 MG	21532530000330	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung origin

AND

2 - One of the following:

- Unresectable, locally advanced disease
- Metastatic disease

AND

3 - Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to generic everolimus tablet

AND

4 - Submission of medical records confirming the formulary alternative(s) has not been effective AND justification/rationale provided explaining how Brand Afinitor is expected to provide benefit when the formulary alternative has not been shown to be effective despite having the same active ingredient

Product Name:Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	TSC-associated Partial-onset Seizures
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 2 MG	21532530007310	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 3 MG	21532530007320	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Brand
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 2 MG	21532530007310	Generic
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 3 MG	21532530007320	Generic
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Generic

Approval Criteria

1 - Diagnosis of TSC-associated partial-onset seizures

AND

2 - Patient is 2 years of age or older

AND

3 - Trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	TSC-associated Partial-onset Seizures
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 2 MG	21532530007310	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 3 MG	21532530007320	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Brand
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 2 MG	21532530007310	Generic
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 3 MG	21532530007320	Generic
EVEROLIMUS	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Generic

Approval Criteria

1 - Patient shows reduction in seizure frequency while on therapy

AND

2 - Trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

Product Name:Brand Afinitor Disperz	
Diagnosis	TSC-associated Partial-onset Seizures
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 2 MG	21532530007310	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 3 MG	21532530007320	Brand
AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of TSC-associated partial-onset seizures

AND

2 - Patient is 2 years of age or older

AND

3 - Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to generic everolimus tablet for oral suspension.

AND

4 - Submission of medical records confirming the formulary alternative(s) has not been effective AND justification/rationale provided explaining how Brand Afinitor Disperz is expected to provide benefit when the formulary alternative has not been shown to be effective despite having the same active ingredient

AND

5 - Prescribed by or in consultation with a neurologist

3 . References

1. Afinitor and Afinitor Disperz Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. February 2022.
2. Torpenz Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN 55369. June 2024.

4 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228785
Guideline Name	Afrezza (insulin human, inhalation powder) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Afrezza (insulin human, inhalation powder)
Diabetes Mellitus Indicated to improve glycemic control in adult patients with diabetes mellitus. Limitations of Use: Afrezza is not recommended for the treatment of diabetic ketoacidosis. The safety and efficacy of Afrezza in patients who smoke has not been established. The use of Afrezza is not recommended in patients who smoke or who have recently stopped smoking.

2 . Criteria

Product Name:Afrezza	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 4 UNIT/CARTRIDGE	27104010002940	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INH POWD 4 & 8 & 12 UNIT/CART (60)	27104010002990	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 12 UNIT/CARTRIDGE	27104010002955	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHAL POWD 90 X 4 UNIT & 90 X 8 UNIT	27104010002978	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INH POWD 90 X 8 UNIT & 90 X 12 UNIT	27104010002988	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 8 UNIT/CARTRIDGE	27104010002950	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of type 1 diabetes mellitus

AND

1.1.2 Used in combination with a long-acting insulin (e.g., Lantus, Levemir)

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

2 - Unable to self-inject short-acting insulin multiple times daily due to one of the following: [4]

- Physical impairment
- Visual impairment

- Lipohypertrophy

AND

3 - Documented FEV1 within the last 60 days greater than or equal to 70% of expected normal as determined by the physician [A]

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Afrezza will NOT be approved in patients:

- Who smoke cigarettes
- Who recently quit smoking (within the past 6 months) [B]
- With chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD]) [C]

Product Name:Afrezza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 4 UNIT/CARTRIDGE	27104010002940	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INH POWD 4 & 8 & 12 UNIT/CART (60)	27104010002990	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 12 UNIT/CARTRIDGE	27104010002955	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHAL POWD 90 X 4 UNIT & 90 X 8 UNIT	27104010002978	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INH POWD 90 X 8 UNIT & 90 X 12 UNIT	27104010002988	Brand

AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 8 UNIT/CARTRIDGE	27104010002950	Brand

Approval Criteria

1 - Repeat pulmonary function test confirms that the patient has NOT experienced a decline of 20% or more in FEV1 from baseline [1]

AND

2 - Patient demonstrates positive clinical response to therapy

AND

3 - Both of the following: [1]

- Patient does NOT have chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD])
- Patient does not smoke cigarettes

Product Name:Afrezza	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 4 UNIT/CARTRIDGE	27104010002940	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INH POWD 4 & 8 & 12 UNIT/CART (60)	27104010002990	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 8 UNIT/CARTRIDGE	27104010002950	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 12 UNIT/CARTRIDGE	27104010002955	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHAL POWD 90 X 4 UNIT & 90 X 8 UNIT	27104010002978	Brand

AFREZZA	INSULIN REGULAR (HUMAN) INH POWD 90 X 8 UNIT & 90 X 12 UNIT	27104010002988	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of type 1 diabetes mellitus

AND

1.1.2 Used in combination with a long-acting insulin (e.g., Lantus, Levemir)

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

2 - Submission of medical records (e.g., chart notes) documenting that patient is unable to self-inject short-acting insulin multiple times daily due to one of the following: [4]

- Physical impairment
- Visual impairment
- Lipohypertrophy

AND

3 - Submission of medical records (e.g., chart notes) documenting FEV1 within the last 60 days greater than or equal to 70% of expected normal as determined by the physician [A]

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Afrezza will NOT be approved in patients:

- Who smoke cigarettes
- Who recently quit smoking (within the past 6 months) [B]
- With chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD]) [C]

Product Name:Afrezza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 4 UNIT/CARTRIDGE	27104010002940	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INH POWD 4 & 8 & 12 UNIT/CART (60)	27104010002990	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 12 UNIT/CARTRIDGE	27104010002955	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHAL POWD 90 X 4 UNIT & 90 X 8 UNIT	27104010002978	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INH POWD 90 X 8 UNIT & 90 X 12 UNIT	27104010002988	Brand
AFREZZA	INSULIN REGULAR (HUMAN) INHALATION POWDER 8 UNIT/CARTRIDGE	27104010002950	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting repeat pulmonary function test confirms that the patient has NOT experienced a decline of 20% or more in FEV1 from baseline [1]

AND

2 - Patient demonstrates positive clinical response to therapy

AND

3 - Both of the following: [1]

- Patient does NOT have chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD])
- Patient does not smoke cigarettes

3 . Endnotes

A. The inclusion criteria for the phase III trial includes the following parameters: Forced expiratory volume in 1 second (FEV1) = 70% of predicted values. [2, 3]
B. The exclusion criteria for the phase III trial excludes current smokers or smoking history within the past 6 months. [2, 3]
C. Afrezza (insulin human) is contraindicated in patients with chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

4 . References

1. Afrezza Prescribing Information. MannKind Corporation. Danbury, CT. February 2023.
2. Bode BW, McGill JB, Lorber DL, et al. Inhaled Technosphere Insulin Compared With Injected Prandial Insulin in Type 1 Diabetes: A Randomized 24-Week Trial. Diabetes Care. 2015 Dec;38(12):2266-73.
3. Rosenstock J, Franco D, Korpachev V, et al. Inhaled Technosphere Insulin Versus Inhaled Technosphere Placebo in Insulin-Naïve Subjects With Type 2 Diabetes Inadequately Controlled on Oral Antidiabetes Agents. Diabetes Care. 2015 Dec;38(12):2274-81.
4. Per clinical consult with endocrinologist, August 6, 2014.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228343
Guideline Name	Agamree (vamorolone)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Agamree (vamorolone)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

2 . Criteria

Product Name:Agamree	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AGAMREE	VAMOROLONE ORAL SUSP 40 MG/ML	22100075001820	Brand

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has received genetic testing for a mutation of the dystrophin gene [A, 2]

AND

4 - One of the following: [A, 2]

4.1 Patient has a confirmed mutation of the dystrophin gene

OR

4.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

5 - Trial and failure or intolerance to both of the following [2]:

- prednisone or prednisolone 0.75 mg/kg/day or 10 mg/kg/weekend [B, 3]
- generic deflazacort oral suspension*

AND

6 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

7 - One of the following:

7.1 For patients less than or equal to 50kg, dose will not exceed 6mg/kg of body weight once daily

OR

7.2 For patients greater than 50kg, dose will not exceed 300mg/day

Notes	*This product may require prior authorization

Product Name:Agamree	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AGAMREE	VAMOROLONE ORAL SUSP 40 MG/ML	22100075001820	Brand

Approval Criteria

1 - Patient has experienced a benefit from therapy (e.g., improvement in preservation of muscle strength)

AND

2 - One of the following:

2.1 For patients less than or equal to 50kg, dose will not exceed 6mg/kg of body weight once daily **OR** **2.2** For patients greater than 50kg, dose will not exceed 300mg/day **AND** **3** - Trial and failure or intolerance to both of the following: [2] • prednisone or prednisolone 0.75 mg/kg/day or 10 mg/kg/weekend [B, 3] • generic deflazacort oral suspension*	
Notes	*This product may require prior authorization

3 . Endnotes

A. Approximately 70% of individuals with DMD have a single-exon or multi-exon deletion or duplication in the dystrophin gene, dystrophin gene deletion, and duplication testing is usually the first confirmatory test. If genetic testing does not confirm a clinical diagnosis of DMD, then a muscle biopsy sample should be tested for the presence of dystrophin protein by immunohistochemistry of tissue cryosections or by western blot of a muscle protein extract. [2]
B. Prednisone 0.75 mg/kg/d should be considered the optimal prednisone dose in DMD. Over 12 months, prednisone 10 mg/kg/weekend is equally effective, although long term outcomes of this alternative regimens are unknown. [3]

4 . References

1. Agamree Prescribing Information. Catalyst Pharmaceuticals, Inc. Coral Gables, FL. October 2023
2. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. The Lancet Neurology. 2018;17(3):251-267.
3. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline

Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(5):465-72.

Prior Authorization Guideline

Guideline ID	GL-229113
Guideline Name	Akeega (niraparib and abiraterone) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/16/2023
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Akeega (niraparib and abiraterone)
Metastatic castration-resistant prostate cancer (mCRPC) In combination with prednisone, indicated for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved test for Akeega.

2 . Criteria

Product Name:Akeega	
Diagnosis	Metastatic castration-resistant prostate cancer (mCRPC)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AKEEGA	NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 50-500 MG	21409902120320	Brand
AKEEGA	NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 100-500 MG	21409902120330	Brand

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - Disease is all of the following:

- Metastatic
- Castration-resistant
- Deleterious or suspected deleterious BRCA-mutated (BRCAm)

AND

3 - Used in combination with prednisone

AND

4 - One of the following:

- Used in combination with a gonadotropin-releasing hormone (GnRH) analog
- Patient has had a bilateral orchiectomy

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to Lynparza (olaparib)

OR

5.2 For continuation of prior therapy

Product Name:Akeega	
Diagnosis	Metastatic castration-resistant prostate cancer (mCRPC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AKEEGA	NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 50-500 MG	21409902120320	Brand
AKEEGA	NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 100-500 MG	21409902120330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Akeega	
Diagnosis	Metastatic castration-resistant prostate cancer (mCRPC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
AKEEGA	NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 50-500 MG	21409902120320	Brand
AKEEGA	NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 100-500 MG	21409902120330	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of prostate cancer

AND

2 - Disease is all of the following:

- Metastatic
- Castration-resistant
- Deleterious or suspected deleterious BRCA-mutated (BRCAm)

AND

3 - Used in combination with prednisone

AND

4 - One of the following:

- Used in combination with a gonadotropin-releasing hormone (GnRH) analog
- Patient has had a bilateral orchiectomy

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Lynparza (olaparib)

OR

5.2 For continuation of prior therapy

3 . References

1. Akeega prescribing information. Janssen Biotech, Inc. Horsham, PA. August 2024.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Aldurazyme (laronidase)

Prior Authorization Guideline

Guideline ID	GL-228346
Guideline Name	Aldurazyme (laronidase)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Aldurazyme (laronidase)
Mucopolysaccharidosis I (MPS I) Indicated for adult and pediatric patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I) and for patients with the Scheie form who have moderate to severe symptoms. The risks and benefits of treating mildly affected patients with the Scheie form have not been established. Aldurazyme has not been evaluated for effects of the central nervous system manifestations of the disorder.

2 . Criteria

Product Name:Aldurazyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALDURAZYME	LARONIDASE SOLN FOR IV INFUSION 2.9 MG/5ML	30906550002020	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Hurler or Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I)

OR

1.2 Diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) in patients with moderate to severe symptoms

Product Name:Aldurazyme	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALDURAZYME	LARONIDASE SOLN FOR IV INFUSION 2.9 MG/5ML	30906550002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Aldurazyme Prescribing Information, BioMarin Pharmaceutical Inc. Novato, CA. December 2019.

Alecensa (alectinib)

Prior Authorization Guideline

Guideline ID	GL-228786
Guideline Name	Alecensa (alectinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Alecensa (alectinib)
Treatment of Metastatic ALK-Positive Non-Small Cell Lung Cancer Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. **Adjuvant Treatment of Resected ALK-Positive Non-Small Cell Lung Cancer** Indicated as adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test

2 . Criteria

Product Name:Alecensa

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALECENSA	ALECTINIB HCL CAP 150 MG (BASE EQUIVALENT)	21530507100120	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer

Notes	*CLIA-certified laboratories: https://wwwn.cdc.gov/clia/Resources/LabSearch.aspx

Product Name:Alecensa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALECENSA	ALECTINIB HCL CAP 150 MG (BASE EQUIVALENT)	21530507100120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Alecensa prescribing information. Genentech. South San Francisco, CA. April 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228787
Guideline Name	Alfa Interferons
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Intron A (interferon alfa-2b)
Hairy Cell Leukemia Indicated for the treatment of patients 18 years of age or older with hairy cell leukemia. **Malignant Melanoma** Indicated as adjuvant to surgical treatment in patients 18 years of age or older with malignant melanoma who are free of disease but at high risk for systemic recurrence, within 56 days of surgery. **Follicular Lymphoma** Indicated for the initial treatment of clinically aggressive follicular Non-Hodgkin's Lymphoma in conjunction with anthracycline-containing combination chemotherapy in patients 18 years of age or older. Efficacy of Intron A therapy in patients with low-grade, low-tumor burden follicular Non-Hodgkin's Lymphoma has not been demonstrated. **Condylomata Acuminata** Indicated for intralesional treatment of selected patients 18 years of age or older with condylomata acuminata involving external surfaces of the genital and perianal areas. The use of this product in adolescents has not been studied. **AIDS-Related Kaposi's Sarcoma** Indicated for the treatment of selected patients 18 years of age or older with AIDS-Related Kaposi's Sarcoma. The likelihood of response to Intron A

therapy is greater in patients who are without systemic symptoms, who have limited lymphadenopathy and who have a relatively intact immune system as indicated by total CD4 count.

Chronic Hepatitis C Indicated for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease who have a history of blood or blood-product exposure and/or are HCV antibody positive. Studies in these patients demonstrated that Intron A therapy can produce clinically meaningful effects on this disease, manifested by normalization of serum alanine aminotransferase (ALT) and reduction in liver necrosis and degeneration. A liver biopsy should be performed to establish the diagnosis of chronic hepatitis. Patients should be tested for the presence of antibody to HCV. Patients with other causes of chronic hepatitis, including autoimmune hepatitis, should be excluded. Prior to initiation of Intron A therapy, the physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before Intron A treatment of patients with chronic hepatitis C: - No history of hepatic encephalopathy, variceal bleeding, ascites, or other clinical signs of decompensation - Bilirubin less than or equal to 2 mg/dL - Albumin stable and within normal limits - Prothrombin time less than 3 seconds prolonged - WBC greater than or equal to 3,000/mm3 - Platelets greater than or equal to 70,000/mm3. Serum creatinine should be normal or near normal. Prior to initiation of Intron A therapy, CBC and platelet counts should be evaluated in order to establish baselines for monitoring potential toxicity. These tests should be repeated at Weeks 1 and 2 following initiation of Intron A therapy, and monthly thereafter. Serum ALT should be evaluated at approximately 3-month intervals to assess response to treatment. Patients with preexisting thyroid abnormalities may be treated if thyroid-stimulating hormone (TSH) levels can be maintained in the normal range by medication. TSH levels must be within normal limits upon initiation of Intron A treatment and TSH testing should be repeated at 3 and 6 months. Intron A in combination with Rebetol is indicated for the treatment of chronic hepatitis C in patients 3 years of age and older with compensated liver disease previously untreated with alpha interferon therapy and in patients 18 years of age and older who have relapsed following alpha interferon therapy. See Rebetol prescribing information for additional information.

Chronic Hepatitis B Indicated for the treatment of chronic hepatitis B in patients 1 year of age or older with compensated liver disease. Patients who have been serum HBsAg positive for at least 6 months and have evidence of HBV replication (serum HBeAg positive) with elevated serum ALT are candidates for treatment. Studies in these patients demonstrated that Intron A therapy can produce virologic remission of this disease (loss of serum HBeAg), and normalization of serum aminotransferases. Intron A therapy resulted in the loss of serum HBsAg in some responding patients. Prior to initiation of Intron A therapy, it is recommended that a liver biopsy be performed to establish the presence of chronic hepatitis and the extent of liver damage. The physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before Intron A treatment of patients with chronic hepatitis B: - No history of hepatic encephalopathy, variceal bleeding, ascites, or other signs of clinical decompensation - Bilirubin normal - Albumin stable and within normal limits - Prothrombin Time - adults < 3 seconds prolonged, pediatrics less than or equal to 2 seconds prolonged - WBC greater than or equal to 4,000/mm^3 - Platelets - adults greater than or equal to 100,000/mm^3, pediatrics greater than or equal to 150,000/mm^3. Patients with causes of chronic hepatitis other than chronic hepatitis B or chronic hepatitis C should not be treated with Intron A. CBC and platelet counts should be evaluated prior to initiation of Intron

A therapy in order to establish baselines for monitoring potential toxicity. These tests should be repeated at treatment Weeks 1, 2, 4, 8, 12, and 16. Liver function tests, including serum ALT, albumin, and bilirubin, should be evaluated at treatment Weeks 1, 2, 4, 8, 12, and 16. HBeAg, HBsAg, and ALT should be evaluated at the end of therapy, as well as 3- and 6-months post-therapy, since patients may become virologic responders during the 6-month period following the end of treatment. In clinical studies in adults, 39% (15/38) of responding patients lost HBeAg 1 to 6 months following the end of Intron A therapy. Of responding patients who lost HBsAg, 58% (7/12) did so 1 to 6 months post-treatment. A transient increase in ALT greater than or equal to 2 x baseline value (flare) can occur during Intron A therapy for chronic hepatitis B. In clinical trials in adults and pediatrics, this flare generally occurred 8 to 12 weeks after initiation of therapy and was more frequent in Intron A responders (adults 63%, 24/38; pediatrics 59%, 10/17) than in non-responders (adults 27%, 13/48; pediatrics 35%, 19/55). However, in adults and pediatrics, elevations in bilirubin 3 mg/dL (2 times ULN) occurred infrequently (adults 2%, 2/86; pediatrics 3%, 2/72) during therapy. When ALT flare occurs, in general, Intron A therapy should be continued unless signs and symptoms of liver failure are observed. During ALT flare, clinical symptomatology and liver function tests including ALT, prothrombin time, alkaline phosphatase, albumin, and bilirubin, should be monitored at approximately 2-week intervals.

Drug Name: Pegasys (peginterferon alfa-2a)

Chronic Hepatitis C 1) Indicated for the treatment of Chronic Hepatitis C (CHC) in combination therapy with other hepatitis C virus drugs for adults with compensated liver disease. PEGASYS monotherapy is indicated only if patient has contraindication or significant intolerance to other HCV drugs. 2) indicated for the treatment of Chronic Hepatitis C (CHC) in combination with ribavirin for pediatric patients 5 years of age and older with compensated liver disease. Limitations of use: Pegasys alone or in combination with ribavirin without additional HCV antiviral drugs is not recommended for treatment of patients with CHC who previously failed therapy with an interferon-alfa. - Pegasys is not recommended for treatment of patients with CHC who have had solid organ transplantation.

Chronic Hepatitis B Indicated for the treatment of adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation. Indicated for the treatment of HBeAg-positive CHB in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine aminotransferase (ALT).

2 . Criteria

Product Name:Intron A	
Diagnosis	Chronic Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INTRON A	INTERFERON ALFA-2B FOR INJ 10000000 UNIT	21700060202130	Brand
INTRON A	INTERFERON ALFA-2B FOR INJ 50000000 UNIT	21700060202160	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C

AND

2 - Patients without decompensated liver disease**

AND

3 - For patients who have not previously been treated with interferon

AND

4 - One of the following:

- Contraindication or intolerance to ribavirin
- Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Notes	**Defined as Child-Pugh Class B or C

Product Name:Pegasys	
Diagnosis	Chronic Hepatitis C
Approval Length	28 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PEGASYS	PEGINTERFERON ALFA-2A INJ 180 MCG/ML	12353060052020	Brand
PEGASYS	PEGINTERFERON ALFA-2A SOLN PREFILLED SYR 180 MCG/0.5ML	1235306005E540	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient without decompensated liver disease**

AND

3 - One of the following:

3.1 Used in combination with one of the following:

- Sovaldi (sofosbuvir)
- Ribavirin

OR

3.2 Contraindication or intolerance to all other HCV agents (e.g., Sovaldi [sofosbuvir], ribavirin)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Notes	**Defined as Child-Pugh Class B or C

Product Name:Pegasys	
Diagnosis	Chronic Hepatitis C
Approval Length	20 Week(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PEGASYS	PEGINTERFERON ALFA-2A INJ 180 MCG/ML	12353060052020	Brand
PEGASYS	PEGINTERFERON ALFA-2A SOLN PREFILLED SYR 180 MCG/0.5ML	1235306005E540	Brand

Approval Criteria

1 - Patient has an undetectable HCV RNA at week 24

AND

2 - Additional treatment weeks of peginterferon are required to complete treatment regimen

AND

3 - Patient has not exceeded 48 weeks of therapy with peginterferon

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Product Name:Intron A or Pegasys	
Diagnosis	Chronic Hepatitis B
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INTRON A	INTERFERON ALFA-2B FOR INJ 10000000 UNIT	21700060202130	Brand
INTRON A	INTERFERON ALFA-2B FOR INJ 50000000 UNIT	21700060202160	Brand
PEGASYS	PEGINTERFERON ALFA-2A INJ 180 MCG/ML	12353060052020	Brand
PEGASYS	PEGINTERFERON ALFA-2A SOLN PREFILLED SYR 180 MCG/0.5ML	1235306005E540	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis B infection

AND

2 - Patients without decompensated liver disease**

Notes	**Defined as Child-Pugh Class B or C

Product Name:Intron A	
Diagnosis	Condylomata acuminata
Approval Length	6 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INTRON A	INTERFERON ALFA-2B FOR INJ 10000000 UNIT	21700060202130	Brand

Approval Criteria

1 - Diagnosis of condylomata acuminata (genital or perianal)

Product Name:Intron A	
Diagnosis	Diagnoses other than hepatitis and condylomata acuminata
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INTRON A	INTERFERON ALFA-2B FOR INJ 10000000 UNIT	21700060202130	Brand
INTRON A	INTERFERON ALFA-2B FOR INJ 50000000 UNIT	21700060202160	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of hairy cell leukemia

OR

1.2 Diagnosis of AIDS-related Kaposi's sarcoma

OR

1.3 Both of the following:

- Diagnosis of metastatic renal cell carcinoma
- Used in combination with Avastin (bevacizumab)

OR

1.4 Diagnosis of malignant melanoma

OR

1.5 Diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma

OR

1.6 As maintenance therapy for the treatment of multiple myeloma (non-FDA approved indication)

3 . References

1. Pegasys Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2021.
2. Intron A Prescribing Information. Merck & Co. Whitehouse Station, NJ. November 2021.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228790
Guideline Name	Alpha-1 Proteinase Inhibitors
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Aralast NP (alpha-1-proteinase inhibitor [human])
Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Aralast NP increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. The effect of augmentation therapy with Alpha1-PI, including Aralast NP, on pulmonary exacerbations and on the progression of emphysema in alpha-1-antitrypsin deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy with Aralast NP or Aralast are not available. Aralast NP is not indicated as therapy for lung disease patients in whom severe congenital Alpha-1-PI deficiency has not been established.
Drug Name: Glassia (alpha-1-proteinase inhibitor [human])
Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in individuals with clinically evident emphysema due to severe hereditary deficiency of Alpha1-PI, also known as alpha1-antitrypsin (AAT) deficiency. Limitations of Use: The effect of augmentation therapy

with Glassia or any Alpha1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with Glassia are not available. Glassia is not indicated as therapy for lung disease in patients in whom severe Alpha1-PI deficiency has not been established.

Drug Name: Prolastin-C (alpha-1-proteinase inhibitor [human]), Prolastin-C liquid (alpha-1-proteinase inhibitor [human])

Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Prolastin-C increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. Limitations of Use: The effect of augmentation therapy with any Alpha-1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with Prolastin-C are not available. Prolastin-C is not indicated as therapy for lung disease in patients in whom severe Alpha-1-PI deficiency has not been established.

Drug Name: Zemaira (alpha-1-proteinase inhibitor [human])

Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in adults with Alpha1-PI deficiency and clinical evidence of emphysema. Zemaira increases antigenic and functional (ANEC) serum levels and lung epithelial lining fluid levels of Alpha1-PI. Clinical data demonstrating the long-term effects of chronic augmentation therapy of individuals with Zemaira are not available. The effect of augmentation therapy with Zemaira or any Alpha1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been demonstrated in randomized, controlled clinical trials. Zemaira is not indicated as therapy for lung disease patients in whom severe Alpha1-PI deficiency has not been established.

2 . Criteria

Product Name:Aralast NP, Glassia, Prolastin-C, Prolastin-C liquid, or Zemaira	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ARALAST NP	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 500 MG	45100010102110	Brand
ARALAST NP	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 1000 MG	45100010102120	Brand
GLASSIA	ALPHA1-PROTEINASE INHIBITOR (HUMAN) INJ 1000 MG/50ML	45100010102020	Brand
PROLASTIN-C	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 1000 MG	45100010102120	Brand
ZEMAIRA	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 1000 MG	45100010102120	Brand
PROLASTIN-C	ALPHA1-PROTEINASE INHIBITOR (HUMAN) INJ 1000 MG/20ML	45100010102015	Brand
ZEMAIRA	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 4000 MG	45100010102140	Brand
ZEMAIRA	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 5000 MG	45100010102150	Brand

Approval Criteria

1 - Diagnosis of congenital alpha-1 antitrypsin (AAT) deficiency

AND

2 - Diagnosis of emphysema [A]

AND

3 - One of the following:

3.1 Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous) [6]

OR

3.2 Other rare AAT disease genotypes associated with pre-treatment serum alpha1-antitrypsin (AAT) level less than 11 micromole per liter [e.g., Pi(Malton, Malton), Pi(SZ)] [B]

AND

4 - One of the following:

4.1 Circulating pre-treatment serum alpha1-antitrypsin (AAT) level less than 11 micromole per liter (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry) [B, 10]

OR

4.2 Patient has a concomitant diagnosis of necrotizing panniculitis

AND

5 - Continued optimal conventional treatment for emphysema (e.g., bronchodilators)

AND

6 - One of the following: [8, 9, 10]

6.1 The FEV1 level is less than or equal to 65% of predicted

OR

6.2 Patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment [9]

OR

6.3 Patient has a concomitant diagnosis of necrotizing panniculitis

AND

7 - Patient is NOT a current smoker [C]

Product Name:Aralast NP, Glassia, Prolastin-C, Prolastin-C liquid, or Zemaira	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ARALAST NP	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 500 MG	45100010102110	Brand
ARALAST NP	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 1000 MG	45100010102120	Brand
GLASSIA	ALPHA1-PROTEINASE INHIBITOR (HUMAN) INJ 1000 MG/50ML	45100010102020	Brand
PROLASTIN-C	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 1000 MG	45100010102120	Brand
ZEMAIRA	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 1000 MG	45100010102120	Brand
PROLASTIN-C	ALPHA1-PROTEINASE INHIBITOR (HUMAN) INJ 1000 MG/20ML	45100010102015	Brand
ZEMAIRA	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 4000 MG	45100010102140	Brand
ZEMAIRA	ALPHA1-PROTEINASE INHIBITOR (HUMAN) FOR IV SOLN 5000 MG	45100010102150	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Continued optimal conventional treatment for emphysema (e.g., bronchodilators)

3 . Endnotes

A. Currently, augmentation therapy is not recommended for patients without emphysema. [3, 8] Some individuals with AAT deficiency will not go on to develop panacinar

emphysema, only those with evidence of such disease should be considered for augmentation therapy.

B. Population studies suggest a minimum plasma threshold of 11 µmol/L (corresponding to 80 mg/dL in some assays and ~57 mg/dL by nephelometry), below which there is insufficient AAT to protect the lung, leading to a risk of developing emphysema. [3, 6-9]
C. The GOLD report recommends reserving alpha-1 antitrypsin augmentation therapy for those with evidence of continued and rapid progression following smoking cessation. [8]

4 . References

1. Aralast NP Prescribing Information. Baxalta US Inc. Westlake Village, CA. March 2023.
2. Zemaira Prescribing Information. CSL Behring LLC. Kankakee, IL. September 2022.
3. American Thoracic Society/European Respiratory Society Statement: Standards for diagnosis and management of individuals with alpha-1 antitrypsin deficiency. Am J Resp Care Med 2003; 168:818-900.
4. Prolastin-C Prescribing Information. Grifols Therapeutics, Inc. Research Triangle Park, NC. January 2022.
5. Glassia Prescribing Information. Baxalta US Inc. Lexington, MA. September 2023.
6. Marciniuk DD, Hernandez P, Balter M, et al. Alpha-1 antitrypsin deficiency targeted testing and augmentation therapy: A Canadian Thoracic Society clinical practice guideline. Canadian Respiratory Journal 2012;19(2):109-116.
7. Stoller JK. Treatment of of alpha-1 antitrypsin deficiency. UpToDate. Accessed March 12, 2019.
8. Vogelmeir C, Agusti A, et al. The global strategy for diagnosis, management and prevention of COPD (2020 Report). Global Initiative for Chronic Obstructive Lung Disease. Accessed January 21, 2020.
9. Brantly ML, Lascano JE, Shahmohammadi A. Intravenous alpha-1 antitrypsin therapy for alpha-1 antitrypsin deficiency: the current state of the evidence. Chronic Obstr Pulm Dis. 2019;6(1):100-114.
10. Sandhaus RA, Turino G, Brantly ML, et al. The diagnosis and management of alpha-1 antitrypsin deficiency in the adult. Chronic Obstr Pulm Dis. 2016; 3(3): 668-682.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228768
Guideline Name	Alunbrig (brigatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Alunbrig (brigatinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

2 . Criteria

Product Name:Alunbrig	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALUNBRIG	BRIGATINIB TAB INITIATION THERAPY PACK 90 MG & 180 MG	2153051000B720	Brand
ALUNBRIG	BRIGATINIB TAB 30 MG	21530510000330	Brand
ALUNBRIG	BRIGATINIB TAB 90 MG	21530510000350	Brand
ALUNBRIG	BRIGATINIB TAB 180 MG	21530510000365	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

Product Name:Alunbrig	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALUNBRIG	BRIGATINIB TAB INITIATION THERAPY PACK 90 MG & 180 MG	2153051000B720	Brand
ALUNBRIG	BRIGATINIB TAB 30 MG	21530510000330	Brand
ALUNBRIG	BRIGATINIB TAB 90 MG	21530510000350	Brand
ALUNBRIG	BRIGATINIB TAB 180 MG	21530510000365	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Alunbrig Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. August 2023.
2. National Comprehensive Cancer Network (NCCN) Non-small cell lung cancer guideline. v.3.2022. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed April 28, 2022.

Prior Authorization Guideline

Guideline ID	GL-228765
Guideline Name	Alvaiz (eltrombopag)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Alvaiz (eltrombopag)
Treatment of Thrombocytopenia in Patients with Persistent or Chronic Immune Thrombocytopenia Indicated for the treatment of thrombocytopenia in adult and pediatric patients 6 years and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. ALVAIZ should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. **Treatment of Thrombocytopenia in Patients with Hepatitis C Infection** Indicated for the treatment of thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. ALVAIZ should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. **Treatment of Severe Aplastic Anemia** Indicated for the treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy. **Limitations of Use** ALVAIZ is not indicated for the treatment of patients with myelodysplastic

syndromes (MDS). Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

2 . Criteria

Product Name:Alvaiz	
Diagnosis	Immune thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALVAIZ	ELTROMBOPAG CHOLINE TAB 9 MG (BASE EQUIV)	82405030050310	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 18 MG (BASE EQUIV)	82405030050320	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 36 MG (BASE EQUIV)	82405030050330	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 54 MG (BASE EQUIV)	82405030050340	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Persistent ITP
- Chronic ITP
- Relapsed/refractory ITP [6]

AND

2 - Baseline platelet count is less than 30,000/mcL

AND

3 - Trial and failure, contraindication, or intolerance to one of the following:

- Corticosteroids
- Immunoglobulins
- Splenectomy

AND

4 - Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Alvaiz	
Diagnosis	Immune thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALVAIZ	ELTROMBOPAG CHOLINE TAB 9 MG (BASE EQUIV)	82405030050310	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 18 MG (BASE EQUIV)	82405030050320	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 36 MG (BASE EQUIV)	82405030050330	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 54 MG (BASE EQUIV)	82405030050340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding

Product Name:Alvaiz	
Diagnosis	Refractory Severe Aplastic Anemia
Approval Length	16 Weeks [B]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALVAIZ	ELTROMBOPAG CHOLINE TAB 9 MG (BASE EQUIV)	82405030050310	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 18 MG (BASE EQUIV)	82405030050320	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 36 MG (BASE EQUIV)	82405030050330	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 54 MG (BASE EQUIV)	82405030050340	Brand

Approval Criteria

1 - Diagnosis of refractory severe aplastic anemia (SAA)

AND

2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy with antithymocyte globulin (ATG) and cyclosporine

AND

3 - Patient has thrombocytopenia defined as platelet count less than 30,000/mcL

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Alvaiz	
Diagnosis	Refractory Severe Aplastic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALVAIZ	ELTROMBOPAG CHOLINE TAB 9 MG (BASE EQUIV)	82405030050310	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 18 MG (BASE EQUIV)	82405030050320	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 36 MG (BASE EQUIV)	82405030050330	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 54 MG (BASE EQUIV)	82405030050340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count

Product Name:Alvaiz	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	3 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALVAIZ	ELTROMBOPAG CHOLINE TAB 9 MG (BASE EQUIV)	82405030050310	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 18 MG (BASE EQUIV)	82405030050320	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 36 MG (BASE EQUIV)	82405030050330	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 54 MG (BASE EQUIV)	82405030050340	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C-associated thrombocytopenia

AND

2 - One of the following:

2.1 Planning to initiate and maintain interferon-based treatment [1]

OR

2.2 Currently receiving interferon-based treatment

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Product Name:Alvaiz	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ALVAIZ	ELTROMBOPAG CHOLINE TAB 9 MG (BASE EQUIV)	82405030050310	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 18 MG (BASE EQUIV)	82405030050320	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 36 MG (BASE EQUIV)	82405030050330	Brand
ALVAIZ	ELTROMBOPAG CHOLINE TAB 54 MG (BASE EQUIV)	82405030050340	Brand

Approval Criteria

1 - One of the following:

1.1 For patients that started treatment with Alvaiz prior to initiation of treatment with interferon, Alvaiz will be approved when both of the following criteria are met:

1.1.1 Currently on antiviral interferon therapy for treatment of chronic hepatitis C [1]

AND

1.1.2 Documentation that the patient reached a threshold platelet count that allows initiation of antiviral interferon therapy with Alvaiz treatment by week 9 [A]

OR

1.2 For patients that started treatment with Alvaiz while on concomitant treatment with interferon, Alvaiz will be approved based on the following criterion:

- Currently on antiviral interferon therapy for treatment of chronic hepatitis C

3 . Endnotes

A. Eltrombopag was studied in two phase 3 trials for chronic hepatitis C-associated thrombocytopenia in two periods. Patients received eltrombopag in the first period for a maximum of 9 weeks in order to achieve a pre-specified threshold platelet count (greater than or equal to 90 x 10^9/L for Trial 1 and greater than or equal to 100 x 10^9/L for Trial 2); if the pre-specified threshold platelet count was reached, eltrombopag was administered in combination with pegylated interferon and ribavirin for up to 48 weeks in the second period. The lowest dose of Alvaiz should be used to achieve and maintain a platelet count necessary to initiate and maintain antiviral therapy with pegylated interferon and ribavirin. Dose adjustments are based upon the platelet count response.[1]

B. In patients with refractory severe aplastic anemia, hematologic response requires dose titration, generally up to 108 mg, and may take up to 16 weeks after starting Alvaiz. The dose should be adjusted every 2 weeks as necessary to achieve the target platelet count greater than or equal to 50 x 10^9/L. If no hematologic response has occurred after 16 weeks of therapy with Alvaiz, therapy should be discontinued. [1]

4 . References

1. Alvaiz Prescribing Information. Teva Pharmaceuticals Inc. Parsippany, NJ 07054. November 2023.
2. Neunert C, Terrell D, Arnold D, et al. The American Society of Hematology 2019 Evidence-based practice guideline for immune thrombocytopenia. Available at: https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for. Accessed March 8, 2024.

3. Bussel JB, Cheng G, Saleh MN, et al. Eltrombopag for the treatment of chronic idiopathic thrombocytopenic purpura. New Engl J Med. 2007;357(22):2237-47.
4. Saleh MN, Bussel JB, Cheng G, et al. Safety and efficacy of eltrombopag for treatment of chronic immune thrombocytopenia: results of the long-term, open-label EXTEND study. 2013;121:537-45.
5. Desmond R, Townsley DM, Dumitriu B, et al. Eltrombopag restores trilineage hematopoiesis in refractory severe aplastic anemia that can be sustained on discontinuation of drug. Blood. 2014;123(12):1818-25.
6. Per clinical consult with hematologist/oncologist. June 20, 2018.
7. Townsley DM, Scheinberg P, Winkler T, et al. Eltrombopag added to standard immunosuppression for aplastic anemia: Supplementary appendix. N Engl J Med 2017;376:1540-50.

Prior Authorization Guideline

Guideline ID	GL-228791
Guideline Name	Ampyra (dalfampridine) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ampyra (dalfampridine)
Improvement in walking in patients with multiple sclerosis Indicated as a treatment to improve walking in adult patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

2 . Criteria

Product Name:Brand Ampyra, Generic dalfampridine extended-release	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AMPYRA	DALFAMPRIDINE TAB SR 12HR 10 MG	62406030007420	Brand
DALFAMPRIDINE ER	DALFAMPRIDINE TAB ER 12HR 10 MG	62406030007420	Generic

Approval Criteria

1 - Diagnosis of multiple sclerosis [A]

AND

2 - Physician confirmation that patient has difficulty walking (e.g., timed 25-foot walk test) [B]

AND

3 - One of the following:

- Patient has an expanded disability status scale (EDSS) score less than or equal to 7
- Patient is not restricted to using a wheelchair (if EDSS is not measured)

AND

4 - For brand Ampyra, trial and failure or intolerance to generic dalfampridine extended-release

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Brand Ampyra, Generic dalfampridine extended-release	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AMPYRA	DALFAMPRIDINE TAB SR 12HR 10 MG	62406030007420	Brand
DALFAMPRIDINE ER	DALFAMPRIDINE TAB ER 12HR 10 MG	62406030007420	Generic

Approval Criteria

1 - Physician confirmation that the patient's walking improved with therapy

AND

2 - One of the following:

- Patient has an expanded disability status scale (EDSS) score less than or equal to 7
- Patient is not restricted to using a wheelchair (if EDSS is not measured)

AND

3 - For brand Ampyra, trial and failure or intolerance to generic dalfampridine extended-release

Product Name:Brand Ampyra	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
AMPYRA	DALFAMPRIDINE TAB SR 12HR 10 MG	62406030007420	Brand

Approval Criteria

1 - Diagnosis of multiple sclerosis [A]

AND

2 - Submission of medical records (e.g., chart notes) documenting physician confirmation that patient has difficulty walking (e.g., timed 25-foot walk test) [B]

AND

3 - Submission of medical records (e.g., chart notes) documenting one of the following:

- Patient has an expanded disability status scale (EDSS) score less than or equal to 7
- Patient is not restricted to using a wheelchair (if EDSS is not measured)

AND

4 - Submission of medical records (e.g., chart notes) documenting trial and failure or intolerance to generic dalfampridine extended-release

AND

5 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. Patients with clinically definite MS of any type were included in the pivotal trials for Ampyra. [2, 3]
B. Inclusion criteria in the Ampyra pivotal trials included patients who were able to walk (with or without an assistive device) 25 feet in 8-45 seconds and 8-60 seconds in the two studies, respectively. [2, 3]

4 . References

1. Ampyra Prescribing Information. Acorda Therapeutics, Inc. Ardsley, NY. November 2021.
2. Goodman AD, Brown TR, Krupp LB, et al. Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial. Lancet 2009;373:732-738.
3. Goodman AD, Brown TR, Cohen JA, et al. Dose comparison trial of sustained-release fampridine in multiple sclerosis. Neurology. 2008;1134-1141.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233324
Guideline Name	Amvuttra (vutrisiran)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/18/2025
P&T Approval Date:	9/21/2022
P&T Revision Date:	9/18/2024

1 . Indications

Drug Name: Amvuttra (vutrisiran)
Hereditary transthyretin-mediated amyloidosis Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

2 . Criteria

Product Name:Amvuttra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AMVUTTRA	VUTRISIRAN SODIUM SOLN PREFILLED SYRINGE 25 MG/0.5ML	6270609010E520	Brand

Approval Criteria

1 - Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy

AND

2 - Patient has a transthyretin (TTR) mutation (e.g., V30M) [1-3]

AND

3 - One of the following [1-4, A, B]:

- Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient has a baseline neuropathy impairment score (NIS) greater than or equal to 5 and less than or equal to 130
- Patient has a baseline Karnofsky Performance Status score greater than or equal to 60%

AND

4 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, walking ability, quality of life) [1-3]

AND

5 - Patient has not had a liver transplant [2-3]

AND

6 - Requested drug is not used in combination with a TTR silencer (e.g.,Tegsedi) or a TTR stabilizer (e.g., Vyndaqel)

AND

7 - Prescribed by or in consultation with a neurologist

Product Name:Amvuttra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AMVUTTRA	VUTRISIRAN SODIUM SOLN PREFILLED SYRINGE 25 MG/0.5ML	6270609010E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms from baseline (e.g., neuropathy, quality of life, gait speed, nutritional status, decrease in serum TTR level)

AND

2 - One of the following [1-4, A, B]:

- Patient continues to have a polyneuropathy disability (PND) score less than or equal to IIIb
- Patient continues to have a familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient continues to have a neuropathy impairment score (NIS) greater than or equal to 5 and less than or equal to 130

- Patient continues to have a Karnofsky Performance Status score greater than or equal to 60%

AND

3 - Requested drug is not used in combination with a TTR silencer (e.g.,Tegsedi) or a TTR stabilizer (e.g., Vyndaqel)

AND

4 - Patient has not had a liver transplant [2-3]

3 . Endnotes

A. The efficacy of vutrisiran was demonstrated in a phase 3, open label, randomized clinical trial (HELIOS-A) in which efficacy endpoints for vutrisiran were compared to an external placebo group from the APOLLO trial. Similar recruitment criteria were used for both HELIOS-A and APOLLO which resulted in similar baseline characteristics between the treatment groups in HELIOS-A and the placebo group in APOLLO [2-3].
B. Baseline characteristics in HELIOS-A included 70% of patients with stage 1 disease and 30% of patients with stage 2 disease [1-2]. The European Medicines Agency lists the full indication for Amvuttra as treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy [4].

4 . References

1. Amvuttra Prescribing Information. Alnylam Pharmaceuticals, Inc. Cambridge, MA. January 2023.
2. Adams D, Tournev IL, Taylor MS, et al. Efficacy and safety of vutrisiran for patients with hereditary transthyretin-mediated amyloidosis with polyneuropathy: a randomized clinical trial. Amyloid. 2022;1-9. Available at https://www.tandfonline.com/doi/full/10.1080/13506129.2022.2091985. Accessed August 4, 2022.
3. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. BMC Neurol. 2017;17:181.
4. Amvuttra. European Medicines Agency Web Site. https://www.ema.europa.eu/en/medicines/human/summaries-opinion/amvuttra. Published July 21, 2022. Accessed August 4, 2022.

5. Velez-Santamaria, V.,Nedkova-Hristova, V., et al. Hereditary Transthyretin Amyloidosis with Polyneuropathy: Monitoring and Management. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9789700/. Accessed August 2, 2023.
6. Carroll, A., Dyck, P., et al. Novel approaches to diagnosis and management of hereditary transthyretin amyloidosis. Available at: https://jnnp.bmj.com/content/93/6/668. Accessed August 2, 2023.

5 . Revision History

Date	Notes
2/18/2025	Quartz commercial copied to mirrow OptumRx.

Prior Authorization Guideline

Guideline ID	GL-228348
Guideline Name	Angiotensin Receptor Blockers
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Edarbi (azilsartan medoxomil)
Hypertension Indicated for the treatment of hypertension to lower blood pressure. Edarbi may be used alone or in combination with other antihypertensive agents.
Drug Name: Edarbyclor (azilsartan and chlorthalidone)
Hypertension Indicated for the treatment of hypertension, to lower blood pressure. Edarbyclor may be used in patients whose blood pressure is not adequately controlled on monotherapy. Edarbyclor may be used as initial therapy if a patient is likely to need multiple drugs to achieve blood pressure goals.
Drug Name: Tekturna HCT (aliskiren and hydrochlorothiazide)
Hypertension Indicated for the treatment of hypertension, to lower blood pressure. Tekturna HCT may be used in patients not adequately controlled with monotherapy. It may also be used as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.

Drug Name: Exforge HCT (amlodipine, valsartan, hydrochlorothiazide)
Hypertension Indicated for the treatment of hypertension, to lower blood pressure. Limitations of use: Exforge HCT is not indicated for the initial therapy of hypertension.

2 . Criteria

Product Name:Edarbi, Edarbyclor, Tekturna HCT	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
EDARBI	AZILSARTAN MEDOXOMIL TAB 80 MG	36150010200330	Brand
EDARBYCLOR	AZILSARTAN MEDOXOMIL-CHLORTHALIDONE TAB 40-12.5 MG	36994002100320	Brand
EDARBYCLOR	AZILSARTAN MEDOXOMIL-CHLORTHALIDONE TAB 40-25 MG	36994002100340	Brand
TEKTURNA HCT	ALISKIREN-HYDROCHLOROTHIAZIDE TAB 150-12.5 MG	36996002150320	Brand
TEKTURNA HCT	ALISKIREN-HYDROCHLOROTHIAZIDE TAB 150-25 MG	36996002150325	Brand
TEKTURNA HCT	ALISKIREN-HYDROCHLOROTHIAZIDE TAB 300-12.5 MG	36996002150340	Brand
TEKTURNA HCT	ALISKIREN-HYDROCHLOROTHIAZIDE TAB 300-25 MG	36996002150345	Brand
EDARBI	AZILSARTAN MEDOXOMIL TAB 40 MG	36150010200320	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) or intolerance to one of the following generics:

- benazepril
- captopril
- enalapril
- fosinopril
- lisinopril
- moexipril
- perindopril
- quinapril
- ramipril
- trandolapril
- benazepril-HCTZ
- captopril-HCTZ
- enalapril-HCTZ
- fosinopril-HCTZ
- lisinopril-HCTZ
- quinapril-HCTZ
- amlodipine-benazepril
- trandolapril-verapamil
- losartan
- losartan-HCTZ
- candesartan
- candesartan-HCTZ
- irbesartan
- irbesartan-HCTZ
- telmisartan
- telmisartan-HCTZ
- amlodipine-olmesartan
- olmesartan
- olmesartan-HCTZ
- olmesartan-amlodipine-HCTZ

Product Name:Exforge HCT	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
EXFORGE HCT	AMLODIPINE-VALSARTAN-HYDROCHLOROTHIAZIDE TAB 5-160-12.5 MG	36994503200320	Brand
EXFORGE HCT	AMLODIPINE-VALSARTAN-HYDROCHLOROTHIAZIDE TAB 5-160-25 MG	36994503200325	Brand

EXFORGE HCT	AMLODIPINE-VALSARTAN-HYDROCHLOROTHIAZIDE TAB 10-160-12.5 MG	36994503200330	Brand
EXFORGE HCT	AMLODIPINE-VALSARTAN-HYDROCHLOROTHIAZIDE TAB 10-160-25 MG	36994503200335	Brand
EXFORGE HCT	AMLODIPINE-VALSARTAN-HYDROCHLOROTHIAZIDE TAB 10-320-25 MG	36994503200340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) or intolerance to one of the following generics:

- amlodipine-olmesartan
- amlodipine-benazepril
- amlodipine-valsartan
- telmisartan-amlodipine
- trandolapril-verapamil
- benazepril-HCTZ
- candesartan-HCTZ
- captopril-HCTZ
- enalapril-HCTZ
- fosinopril-HCTZ
- lisinopril-HCTZ
- losartan-HCTZ
- olmesartan-HCTZ
- quinapril-HCTZ
- telmisartan-HCTZ
- olmesartan-amlodipine-HCTZ

3 . References

1. Edarbi prescribing information. Azurity Pharmaceuticals. Atlanta, GA. January 2024.
2. Edarbyclor prescribing information. Azurity Pharmaceuticals. Atlanta, GA. March 2023.
3. Tekturna HCT prescribing information. Noden Pharma USA, Inc. Boston, MA. May 2023.
4. Exforge HCT prescribing information. Novartis Pharmaceuticals Corp. East Hanover, New Jersey. May 2023.

Anktiva (nogapendekin alfa inbakicept-pmln)

Prior Authorization Guideline

Guideline ID	GL-229068
Guideline Name	Anktiva (nogapendekin alfa inbakicept-pmln)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Anktiva (nogapendekin alfa inbakicept-pmln)
non-Muscle Invasive Bladder Cancer (NMIBC) Indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

2 . Criteria

Product Name:Anktiva	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ANKTIVA	NOGAPENDEKIN ALFA INBAK-PMLN INTRAVESICAL SOLN 400 MCG/0.4ML	21703055652020	Brand

Approval Criteria

1 - Diagnosis of non-Muscle Invasive Bladder Cancer (NMIBC)

AND

2 - One of the following:

- Tumor is carcinoma in situ (CIS)
- Ta/T1 high grade disease

AND

3 - Patient is not eligible for or has elected not to undergo cystectomy

AND

4 - Patient has received an adequate course of Bacillus Calmette Guérin (BCG) monotherapy defined as the administration of at least 5 of 6 doses of an initial induction course plus one of the following:

- At least two of three doses of maintenance therapy
- At least two of six doses of a second induction course

AND

5 - Tumor is unresponsive to BCG monotherapy as defined by one of the following:

- Persistent disease following adequate BCG therapy
- Disease recurrence after an initial tumor-free state following adequate BCG therapy
- T1 disease following a single induction course of BCG

AND

6 - Medication is used in combination with Bacillus Calmette-Guérin (BCG) therapy

AND

7 - The patient has had all resectable disease (Ta and T1 components) removed

AND

8 - The patient does not have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma

Product Name:Anktiva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ANKTIVA	NOGAPENDEKIN ALFA INBAK-PMLN INTRAVESICAL SOLN 400 MCG/0.4ML	21703055652020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Anktiva prescribing information. AGC Biologics. Bothell, WA. April 2024.
2. Chamie, K., Chang, S., Kramolowsky, E., et al. IL-15 Superagonist NAI in BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer. Available at: https://evidence.nejm.org/doi/full/10.1056/EVIDoa2200167. Accessed June 17, 2024.
3. ClinicalTrials.gov. QUILT-3.032: A Multicenter Clinical Trial of Intravesical Bacillus Calmette-Guerin (BCG) in Combination With ALT-803 (N-803) in Patients With BCG Unresponsive High Grade Non-Muscle Invasive Bladder Cancer. Available at:

https://www.clinicaltrials.gov/study/NCT03022825?cond=nct03022825&rank=1. Accessed June 17, 2024.

4 . Revision History

Date	Notes
11/19/2024	2025 Implementation

Prior Authorization Guideline

Guideline ID	GL-233369
Guideline Name	Anti-Parkinson’s Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	5/22/1998
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Rytary (carbidopa and levodopa) extended-release capsules
Parkinson’s disease Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication
Drug Name: Duopa (carbidopa and levodopa) enteral suspension
Advanced Parkinson's disease Indicated for the treatment of motor fluctuations in patients with advanced Parkinson’s disease.
Drug Name: Xadago (safinamide) tablets
Parkinson’s disease Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.

Drug Name: Gocovri (amantadine) extended-release capsules
Dyskinesia in Parkinson's disease Indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. **"Off" Episodes in Parkinson's Disease** Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease experiencing “off” episodes.
Drug Name: Osmolex ER (amantadine) extended-release tablets
Parkinson's Disease Indicated for the treatment of Parkinson's disease. **Drug-Induced Extrapyramidal Reactions** Indicated for the treatment of drug-induced extrapyramidal reactions in adult patients.
Drug Name: Dhivy (carbidopa-levodopa)
Parkinson's Disease Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and symptomatic parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.
Drug Name: Crexont (carbidopa and levodopa) extended-release capsules
Parkinson's Disease Indicated for the treatment of Parkinson’s disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication in adults.
Drug Name: Ongentys (opicapone)
Parkinson’s Disease Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease (PD) experiencing “off” episodes.
Drug Name: Vyalev (foscarbidopa and foslevodopa) subcutaneous injection
Advanced Parkinson’s disease Indicated for the treatment of motor fluctuations in adults with advanced Parkinson’s disease.

2 . Criteria

Product Name:Crexont, Rytary	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
RYTARY	CARBIDOPA & LEVODOPA CAP CR 23.75-95 MG	73209902100220	Brand
RYTARY	CARBIDOPA & LEVODOPA CAP CR 36.25-145 MG	73209902100230	Brand
RYTARY	CARBIDOPA & LEVODOPA CAP CR 48.75-195 MG	73209902100240	Brand
RYTARY	CARBIDOPA & LEVODOPA CAP CR 61.25-245 MG	73209902100250	Brand
CREXONT	CARBIDOPA & LEVODOPA CAP ER 35-140 MG	73209902100228	Brand
CREXONT	CARBIDOPA & LEVODOPA CAP ER 52.5-210 MG	73209902100244	Brand
CREXONT	CARBIDOPA & LEVODOPA CAP ER 70-280 MG	73209902100255	Brand
CREXONT	CARBIDOPA & LEVODOPA CAP ER 87.5-350 MG	73209902100265	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) of ONE of the following:

- Generic carbidopa-levodopa immediate release
- Generic carbidopa-levodopa extended release

Product Name:Xadago	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
XADAGO	SAFINAMIDE	73300028200330	Brand
XADAGO	SAFINAMIDE	73300028200320	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) of BOTH of the following:

- rasagiline mesylate
- selegiline

Product Name:Duopa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUOPA	CARBIDOPA-LEVODOPA ENTERAL SUSP 4.63-20 MG/ML	73209902101820	Brand

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is levodopa-responsive [A, B]

AND

3 - Patient experiences disabling “Off” periods for a minimum of 3 hours/day [B]

AND

4 - Disabling “Off" periods occur despite therapy with both of the following: [A, C]

- Oral levodopa-carbidopa
- One drug from a different class of anti-Parkinson's disease therapy (e.g., COMT inhibitor [entacapone, tolcapone], MAO-B inhibitor [selegiline, rasagiline], dopamine agonist [pramipexole, ropinirole])

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Duopa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUOPA	CARBIDOPA-LEVODOPA ENTERAL SUSP 4.63-20 MG/ML	73209902101820	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Gocovri	
Diagnosis	Dyskinesia in Parkinson’s Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GOCOVRI	AMANTADINE HCL CAP ER 24HR 68.5 MG (BASE EQUIVALENT)	73200010107020	Brand
GOCOVRI	AMANTADINE HCL CAP ER 24HR 137 MG (BASE EQUIVALENT)	73200010107040	Brand

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing dyskinesia

AND

3 - Patient is receiving concurrent levodopa-based therapy [5, D]

AND

4 - Trial and failure or intolerance to amantadine immediate release

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Gocovri	
Diagnosis	"Off" Episodes in Parkinson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GOCOVRI	AMANTADINE HCL CAP ER 24HR 68.5 MG (BASE EQUIVALENT)	73200010107020	Brand
GOCOVRI	AMANTADINE HCL CAP ER 24HR 137 MG (BASE EQUIVALENT)	73200010107040	Brand

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing "off" episodes [E, 6]

AND

3 - Used in combination with levodopa/carbidopa therapy [1]

AND

4 - Both of the following:

4.1 Trial and failure, or intolerance to amantadine immediate release

AND

4.2 Trial and failure, contraindication or intolerance to one of the following:

- MAO-B inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT inhibitor (e.g., entacapone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Gocovri	
Diagnosis	All Indications
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GOCOVRI	AMANTADINE HCL CAP ER 24HR 68.5 MG (BASE EQUIVALENT)	73200010107020	Brand
GOCOVRI	AMANTADINE HCL CAP ER 24HR 137 MG (BASE EQUIVALENT)	73200010107040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decreased "off" periods, decreased "on" time with troublesome dyskinesia) [D]

Product Name:Osmolex ER	
Diagnosis	Parkinson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OSMOLEX ER	AMANTADINE HCL TAB ER 24HR 129 MG (BASE EQUIVALENT)	73200010107520	Brand
OSMOLEX ER	AMANTADINE HCL TAB ER 24HR 193 MG (BASE EQUIVALENT)	73200010107530	Brand
OSMOLEX ER	AMANTADINE HCL TAB ER 24HR PAK 129 MG & 193 MG (322 MG DOSE)	7320001010C320	Brand

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Trial and failure, contraindication or intolerance to BOTH of the following:

2.1 amantadine immediate release

AND

2.2 ONE of the following: [9]

- carbidopa-levodopa
- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Osmolex ER	
Diagnosis	Drug-Induced Extrapyramidal Reactions
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OSMOLEX ER	AMANTADINE HCL TAB ER 24HR 129 MG (BASE EQUIVALENT)	73200010107520	Brand
OSMOLEX ER	AMANTADINE HCL TAB ER 24HR 193 MG (BASE EQUIVALENT)	73200010107530	Brand
OSMOLEX ER	AMANTADINE HCL TAB ER 24HR PAK 129 MG & 193 MG (322 MG DOSE)	7320001010C320	Brand

Approval Criteria

1 - Patient is experiencing drug-induced extrapyramidal reactions

AND

2 - One of the following: [10]

2.1 Patient has persistent extrapyramidal symptoms despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Trial and failure or intolerance to amantadine immediate release

AND

4 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name:Osmolex ER	
Diagnosis	Parkinson's Disease, Drug-Induced Extrapyramidal Reactions
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OSMOLEX ER	AMANTADINE HCL TAB ER 24HR 129 MG (BASE EQUIVALENT)	73200010107520	Brand
OSMOLEX ER	AMANTADINE HCL TAB ER 24HR 193 MG (BASE EQUIVALENT)	73200010107530	Brand
OSMOLEX ER	AMANTADINE HCL TAB ER 24HR PAK 129 MG & 193 MG (322 MG DOSE)	7320001010C320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Dhivy	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
DHIVY	CARBIDOPA & LEVODOPA TAB 25-100	73209902100320	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) of both of the following:

- Generic carbidopa-levodopa immediate release (IR)
- Generic carbidopa-levodopa oral disintegrating tablet (ODT)

Product Name:Ongentys	
Diagnosis	Parkinson's Disease
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ONGENTYS	OPICAPONE CAP 25 MG	73153060000110	Brand
ONGENTYS	OPICAPONE CAP 50 MG	73153060000120	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (to a minimum 30 day supply), contraindication, or intolerance to entacapone

Product Name:Vyalev	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYALEV	FOSLEVODOPA-FOSCARBIDOPA SUBCUTANEOUS INJ 240-12 MG/ML	73209902132020	Brand

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is levodopa-responsive

AND

3 - Patient experiences disabling “Off” periods for a minimum of 2.5 hours/day

AND

4 - Disabling “Off" periods occur despite therapy with both of the following:

- Oral levodopa-carbidopa
- One drug from a different class of anti-Parkinson's disease therapy (e.g., COMT inhibitor [entacapone, tolcapone], MAO-B inhibitor [selegiline, rasagiline], dopamine agonist [pramipexole, ropinirole])

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Vyalev	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYALEV	FOSLEVODOPA-FOSCARBIDOPA SUBCUTANEOUS INJ 240-12 MG/ML	73209902132020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. The efficacy of Duopa was established in a randomized, double-blind, double-dummy, active controlled, parallel group, 12-week study in patients with advanced Parkinson's disease who were levodopa-responsive and had persistent motor fluctuations while on treatment with oral immediate-release carbidopa-levodopa and other Parkinson's disease medications. [2, 3]
B. Patients were eligible for participation in the studies if they were experiencing 3 hours or more of “Off” time on their current Parkinson's disease drug treatment and they demonstrated a clear responsiveness to treatment with levodopa. [2, 3]
C. Most patients (89%) were taking at least one concomitant medication for Parkinson’s disease (e.g., dopaminergic agonist, COMT-inhibitor, MAO B inhibitor) in addition to oral immediate-release carbidopa-levodopa. [2, 3]
D. The efficacy of Gocovri was established in two Phase III randomized, double-blind, placebo-controlled trials, a 12 week and 24 week study in patients with Parkinson's

disease were treated with levodopa. Both studies demonstrate statistically significant and clinically relevant reduction in dyskinesia compared to placebo. Also, both studies showed that Gocovri-treated patients experienced an increase in functional time daily (defined as ON time without troublesome dyskinesia) compared to placebo-treated patients. [6, 7]

E. “Off” time is defined as the amount of time the Parkinson’s Disease medication was not controlling motor symptoms. [6]

4 . References

1. Duopa Prescribing Information. AbbVie Inc. North Chicago, IL. December 2019.
2. Olanow CW, Kieburtz K, Odin P, et al. Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson’s disease: a randomised, controlled, double-blind, double-dummy study. Lancet Neurol. 2014 Feb;13(2):141-9.
3. Rytary Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. December 2019.
4. Xadago Prescribing Information. US WorldMeds, LLC. Louisville, KY. August 2021.
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6. Pahwa R, Tanner CM, Hauser RA, et al. ADS-5102 (Amantadine) Extended- Release Capsules for Levodopa-Induced Dyskinesia in Parkinson Disease (EASE LID Study): A Randomized Clinical Trial. JAMA Neurol. 2017 Aug:1;74(8): 941-949.
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8. Osmolex ER Prescribing Information. Vertical Pharmaceuticals, LLC. Bridgewater, NJ. March 2021.
9. National Institute of Health and Clinical Excellence (NICE). Parkinson's disease in adults. NICE guideline [NG71]. July 2017. Available at: https://www.nice.org.uk/guidance/ng71/chapter/Recommendations. Accessed January 28, 2021.
10. Muench J, Hamer AM. Adverse effects of antipsychotic medications. Am Fam Physician. 2010 Mar 1;81(5):617-622.
11. Oertel W, Eggert K, Pahwa R, et al. Randomized, placebo-controlled trial of ADS-5102 (amantadine) extended-release capsules for levodopa-induced dyskinesia in Parkinson's disease (EASE LID 3). Mov Disord. 2017;32(12):1701-1709.
12. Dhivy Prescribing Information. Riverside Pharmaceuticals Corporation. Washington, DC. November 2021.
13. Zahoor, I., Shafi, A., Ehtishamul, H. Pharmacological Treatment of Parkinson’s Disease. Available at: https://www.ncbi.nlm.nih.gov/books/NBK536726/. Accessed February 9, 2024.
14. UpToDate. Initial pharmacologic treatment of Parkinson disease. Available at: https://www.uptodate.com/contents/initial-pharmacologic-treatment-of-parkinson-disease?search=parkinsons%20disease%20adult%20treatment&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed February 9, 2024.
15. Crexont Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. August 2024.
16. Ongentys prescribing information. Neurocrine Biosciences, Inc. San Diego, CA. April 2020.

17. Vyalev Prescribing Information. AbbVie Inc. North Chicago, IL. October 2024.

5 . Revision History

Date	Notes
3/6/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-228349
Guideline Name	Anticonvulsants
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Trokendi XR (topiramate extended-release)
Monotherapy Epilepsy Indicated as initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older **Adjunctive Therapy Epilepsy** Indicated as adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older **Migraine** Indicated for the preventive treatment of migraine in patients 12 years of age and older
Drug Name: Qudexy XR (topiramate extended-release)
Monotherapy Epilepsy Indicated as initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older. **Adjunctive Therapy Epilepsy** Indicated as adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut Syndrome in patients 2 years of age and older.

Migraine Indicated for the preventive treatment of migraine in patients 12 years of age and older.
Drug Name: Eprontia (topiramate oral solution)
Monotherapy Epilepsy Indicated as initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older. **Adjunctive Therapy Epilepsy** Indicated as adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older. **Migraine** Indicated for the preventive treatment of migraine in patients 12 years and older.
Drug Name: Oxtellar XR (oxcarbazepine extended-release)
Partial-onset seizures Indicated for the treatment of partial-onset seizures in patients 6 years of age and older.
Drug Name: Briviact (brivaracetam)
Partial-onset seizures Indicated for the treatment of partial-onset seizures in patients 1 month of age and older.
Drug Name: Xcopri (cenobamate)
Partial-onset seizures Indicated for the treatment of partial-onset seizures in adult patients.
Drug Name: Elepsia XR (levetiracetam extended-release)
Partial-onset seizures Indicated as adjunctive therapy for the treatment of partial-onset seizures in patients 12 years of age and older.
Drug Name: Motpoly XR (lacosamide extended-release)
Partial-onset seizures Indicated for the treatment of partial-onset seizures in adults and pediatric patients weighing at least 50 kg.

2 . Criteria

Product Name:Brand Qudexy XR, Brand Trokendi XR, generic topiramate ER	
Approval Length	12 month(s)

Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TROKENDI XR	TOPIRAMATE CAP SR 24HR 25 MG	72600075007020	Brand
TROKENDI XR	TOPIRAMATE CAP SR 24HR 50 MG	72600075007030	Brand
TROKENDI XR	TOPIRAMATE CAP SR 24HR 100 MG	72600075007040	Brand
TROKENDI XR	TOPIRAMATE CAP SR 24HR 200 MG	72600075007050	Brand
QUDEXY XR	TOPIRAMATE CAP ER 24HR SPRINKLE 25 MG	7260007500F310	Brand
QUDEXY XR	TOPIRAMATE CAP ER 24HR SPRINKLE 50 MG	7260007500F320	Brand
QUDEXY XR	TOPIRAMATE CAP ER 24HR SPRINKLE 100 MG	7260007500F330	Brand
QUDEXY XR	TOPIRAMATE CAP ER 24HR SPRINKLE 150 MG	7260007500F340	Brand
QUDEXY XR	TOPIRAMATE CAP ER 24HR SPRINKLE 200 MG	7260007500F350	Brand
TOPIRAMATE ER	TOPIRAMATE CAP ER 24HR 25 MG	72600075007020	Generic
TOPIRAMATE ER	TOPIRAMATE CAP ER 24HR 50 MG	72600075007030	Generic
TOPIRAMATE ER	TOPIRAMATE CAP ER 24HR 100 MG	72600075007040	Generic
TOPIRAMATE ER	TOPIRAMATE CAP ER 24HR 200 MG	72600075007050	Generic

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30 day supply) or intolerance to generic topiramate immediate-release (IR) tablet or topiramate IR sprinkle capsule.

OR

2 - For continuation of prior therapy

Product Name:Eprontia	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
EPRONTIA	TOPIRAMATE ORAL SOLN 25 MG/ML	72600075002020	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30 day supply) or intolerance to generic topiramate IR sprinkle capsules

OR

2 - For continuation of prior therapy

Product Name:Brand Oxtellar XR, Generic oxcarbazepine extended-release	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
OXTELLAR XR	OXCARBAZEPINE TAB ER 24HR 150 MG	72600046007520	Brand
OXTELLAR XR	OXCARBAZEPINE TAB ER 24HR 300 MG	72600046007530	Brand
OXTELLAR XR	OXCARBAZEPINE TAB ER 24HR 600 MG	72600046007540	Brand

OXCARBAZEPINE ER	OXCARBAZEPINE TAB ER 24HR 150 MG	72600046007520	Generic
OXCARBAZEPINE ER	OXCARBAZEPINE TAB ER 24HR 300 MG	72600046007530	Generic
OXCARBAZEPINE ER	OXCARBAZEPINE TAB ER 24HR 600 MG	72600046007540	Generic

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30 day supply) or intolerance to generic oxcarbazepine immediate-release (IR)

OR

2 - For continuation of prior therapy

Product Name:Briviact	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
BRIVIACT	BRIVARACETAM TAB 10 MG	72600015000310	Brand
BRIVIACT	BRIVARACETAM TAB 25 MG	72600015000320	Brand
BRIVIACT	BRIVARACETAM TAB 50 MG	72600015000330	Brand
BRIVIACT	BRIVARACETAM TAB 75 MG	72600015000340	Brand
BRIVIACT	BRIVARACETAM TAB 100 MG	72600015000350	Brand
BRIVIACT	BRIVARACETAM ORAL SOLN 10 MG/ML	72600015002020	Brand
BRIVIACT	BRIVARACETAM IV SOLN 50 MG/5ML	72600015002050	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication or intolerance to one of the following generics:

- lamotrigine immediate-release (IR)
- levetiracetam IR
- levetiracetam extended-release (ER)
- oxcarbazepine IR
- topiramate IR

OR

2 - For continuation of prior therapy

Product Name:Xcopri	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
XCOPRI	CENOBAMATE TAB TITRATION PACK 14 X 12.5 MG & 14 X 25 MG	7212001000B720	Brand
XCOPRI	CENOBAMATE TAB TITRATION PACK 14 X 50 MG & 14 X 100 MG	7212001000B725	Brand
XCOPRI	CENOBAMATE TAB TITRATION PACK 14 X 150 MG & 14 X 200 MG	7212001000B730	Brand
XCOPRI	CENOBAMATE TAB PACK 50 MG & 200 MG TABS (250 MG DAILY DOSE)	7212001000B735	Brand
XCOPRI	CENOBAMATE TAB PACK 150 MG & 200 MG TABS (350 MG DAILY DOSE)	7212001000B740	Brand

XCOPRI	CENOBAMATE TAB 50 MG	72120010000320	Brand
XCOPRI	CENOBAMATE TAB 100 MG	72120010000325	Brand
XCOPRI	CENOBAMATE TAB 150 MG	72120010000330	Brand
XCOPRI	CENOBAMATE TAB 200 MG	72120010000335	Brand
XCOPRI	CENOBAMATE TAB PACK 100 MG & 150 MG TABS (250 MG DAILY DOSE)	7212001000B738	Brand
XCOPRI	CENOBAMATE TAB 25 MG	72120010000310	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication or intolerance to one of the following generics:

- lamotrigine immediate-release (IR)
- levetiracetam IR
- levetiracetam extended-release (ER)
- oxcarbazepine IR
- topiramate IR

OR

2 - For continuation of prior therapy

Product Name:Elepsia XR	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic

ELEPSIA XR	LEVETIRACETAM TAB ER 24HR 1000 MG	72600043007550	Brand
ELEPSIA XR	LEVETIRACETAM TAB ER 24HR 1500 MG	72600043007570	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30 day supply) or intolerance to generic levetiracetam extended-release

OR

2 - For continuation of prior therapy

Product Name:Motpoly XR	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
MOTPOLY XR	LACOSAMIDE CAP ER 24HR 100 MG	72600036007020	Brand
MOTPOLY XR	LACOSAMIDE CAP ER 24HR 150 MG	72600036007025	Brand
MOTPOLY XR	LACOSAMIDE CAP ER 24HR 200 MG	72600036007030	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30 day supply) or intolerance to generic lacosamide IR

OR

2 - For continuation of prior therapy

3 . References

1. Trokendi XR Prescribing Information. Supernus Pharmaceuticals, Inc. Rockville, MD. December 2020.
2. Qudexy XR Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN. September 2020.
3. Oxtellar XR Prescribing Information. Supernus Pharmaceuticals, Inc. Rockville, MD. December 2020.
4. Briviact Prescribing Information. UCB, Inc. Smyrna, GA. September 2021.
5. Xcopri Prescibing Information. SK Life Science, Inc. Paramus, NJ. April 2021.
6. Elepsia XR Prescribing Information. Tripoint Therapeutics, LLC. Westfield, NJ. December 2020.
7. Eprontia Prescribing Information. Tulex Pharmaceuticals, Inc. Cranbury Township, NJ. November 2021.
8. Motpoly XR Prescribing Information. Aucta Pharmaceuticals, Inc. Piscataway, NJ. May 2023.

Prior Authorization Guideline

Guideline ID	GL-229115
Guideline Name	Antiemetics Quantity Limit Overrides
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/25/2016
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Akynzeo (netupitant/palonosetron)
Chemotherapy-induced nausea and vomiting AKYNZEO capsules is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. AKYNZEO capsules is a combination of palonosetron and netupitant: palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy. AKYNZEO for injection and AKYNZEO injection are indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy. AKYNZEO for injection is a combination of palonosetron and fosnetupitant, a prodrug of netupitant: palonosetron prevents nausea and vomiting during the acute phase and fosnetupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy. Limitations of Use: AKYNZEO for injection and AKYNZEO injection

have not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy.

Drug Name: Anzemet (dolasetron)

Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses in adults and children 2 years and older.

Off Label Uses: Radiotherapy-induced nausea and vomiting Used for the prevention and treatment of nausea and vomiting induced by radiation therapy. [11, 12]

Postoperative nausea and vomiting Used orally for the prevention of postoperative nausea and vomiting. [13]

Drug Name: Emend (aprepitant)

Chemotherapy-induced nausea and vomiting Indicated, in combination with other antiemetic agents, in patients 6 months of age and older for oral suspension, or 12 years of age and older for the capsules, for the prevention of: (1) acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin; (2) nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). Limitations of Use: (1) Emend has not been studied for the treatment of established nausea and vomiting; (2) Chronic continuous administration of Emend is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use.

Postoperative Nausea and Vomiting - capsules only Indicated in adults for the prevention of postoperative nausea and vomiting. Limitations of Use: (1) Emend has not been studied for the treatment of established nausea and vomiting; (2) Chronic continuous administration of Emend is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use.

Drug Name: Granisetron

Chemotherapy-induced nausea vomiting Indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.

Radiation-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

Off Label Uses: Postoperative nausea and vomiting Used for the prevention of postoperative nausea and vomiting. [14, 15]

Drug Name: Marinol (dronabinol)

Chemotherapy-induced nausea and vomiting Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to

respond adequately to conventional antiemetic treatments.

Anorexia in patients with AIDS Indicated in adults for the treatment of anorexia associated with weight loss in patients with AIDS.

Drug Name: Sancuso (granisetron transdermal system)

Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting in adults receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days duration.

Drug Name: Sustol (granisetron injection)

Chemotherapy-induced nausea and vomiting Indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

Drug Name: Varubi (rolapitant)

Chemotherapy-induced nausea and vomiting Indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

Drug Name: Zofran (ondansetron)

Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m2. Also indicated for the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

Radiotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.

Postoperative nausea and vomiting Indicated for the prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, Zofran Tablets, Zofran ODT Orally Disintegrating Tablets, Zofran Oral Solution, and Zuplenz are recommended even where the incidence of postoperative nausea and/or vomiting is low.

Off Label Uses: Hyperemesis gravidarum Used in the management of hyperemesis gravidarum. [10, 16]

2 . Criteria

Product Name:Akynzeo, Anzemet, eneric dronabinol, Brand Emend, Generic aprepitant, granisetron, Brand Marinol, Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Sancuso, Sustol, or Varubi	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
AKYNZEO	NETUPITANT-PALONOSETRON CAP 300-0.5 MG	50309902290120	Brand
ANZEMET	DOLASETRON MESYLATE TAB 50 MG	50250025200320	Brand
ANZEMET	DOLASETRON MESYLATE TAB 100 MG	50250025200330	Brand
EMEND	APREPITANT CAPSULE 40 MG	50280020000110	Brand
EMEND	APREPITANT CAPSULE 80 MG	50280020000120	Brand
EMEND	APREPITANT CAPSULE 125 MG	50280020000130	Brand
EMEND	APREPITANT CAPSULE THERAPY PACK 80 & 125 MG	50280020006320	Brand
GRANISETRON HCL	GRANISETRON HCL TAB 1 MG	50250035100310	Generic
MARINOL	DRONABINOL CAP 2.5 MG	50300030000110	Brand
DRONABINOL	DRONABINOL CAP 2.5 MG	50300030000110	Generic
MARINOL	DRONABINOL CAP 5 MG	50300030000115	Brand
DRONABINOL	DRONABINOL CAP 5 MG	50300030000115	Generic
MARINOL	DRONABINOL CAP 10 MG	50300030000120	Brand
DRONABINOL	DRONABINOL CAP 10 MG	50300030000120	Generic
SANCUSO	GRANISETRON TD PATCH 3.1 MG/24HR (CONTAINS 34.3 MG)	50250035005920	Brand
ONDANSETRON ODT	ONDANSETRON ORALLY DISINTEGRATING TAB 4 MG	50250065007220	Generic
ONDANSETRON ODT	ONDANSETRON ORALLY DISINTEGRATING TAB 8 MG	50250065007240	Generic
ONDANSETRON HCL	ONDANSETRON HCL ORAL SOLN 4 MG/5ML	50250065052070	Generic
ONDANSETRON HCL	ONDANSETRON HCL TAB 24 MG	50250065050340	Generic
SUSTOL	GRANISETRON EXTENDED RELEASE INJ PREFILLED SYR 10 MG/0.4ML	5025003500E420	Brand

APREPITANT	APREPITANT CAPSULE 40 MG	50280020000110	Generic
APREPITANT	APREPITANT CAPSULE 80 MG	50280020000120	Generic
APREPITANT	APREPITANT CAPSULE 125 MG	50280020000130	Generic
APREPITANT	APREPITANT CAPSULE THERAPY PACK 80 & 125 MG	50280020006320	Generic
VARUBI (180 MG DOSE)	ROLAPITANT HCL TAB THERAPY PACK 2 X 90 MG (BASE EQUIV)	5028005020B720	Brand

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Patient is receiving moderately to highly emetogenic chemotherapy

AND

3 - Provider attests that a higher quantity is needed due to the number of chemotherapy sessions

Product Name:Anzemet, granisetron, Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, or Generic ondansetron ODT	
Diagnosis	Radiotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
ANZEMET	DOLASETRON MESYLATE TAB 50 MG	50250025200320	Brand
ANZEMET	DOLASETRON MESYLATE TAB 100 MG	50250025200330	Brand
GRANISETRON HCL	GRANISETRON HCL TAB 1 MG	50250035100310	Generic
ONDANSETRON ODT	ONDANSETRON ORALLY DISINTEGRATING TAB 4 MG	50250065007220	Generic

ONDANSETRON ODT	ONDANSETRON ORALLY DISINTEGRATING TAB 8 MG	50250065007240	Generic
ONDANSETRON HCL	ONDANSETRON HCL ORAL SOLN 4 MG/5ML	50250065052070	Generic
ONDANSETRON HCL	ONDANSETRON HCL TAB 24 MG	50250065050340	Generic

Approval Criteria

1 - Diagnosis of radiotherapy-induced nausea and vomiting

AND

2 - Patient is receiving radiotherapy consisting of total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen

AND

3 - Provider attests that a higher quantity is needed due to the number of radiation sessions

Product Name:Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, or Generic ondansetron ODT	
Diagnosis	Hyperemesis gravidarum
Approval Length	6 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
ONDANSETRON ODT	ONDANSETRON ORALLY DISINTEGRATING TAB 4 MG	50250065007220	Generic
ONDANSETRON ODT	ONDANSETRON ORALLY DISINTEGRATING TAB 8 MG	50250065007240	Generic
ONDANSETRON HCL	ONDANSETRON HCL ORAL SOLN 4 MG/5ML	50250065052070	Generic
ONDANSETRON HCL	ONDANSETRON HCL TAB 24 MG	50250065050340	Generic
ONDANSETRON HYDROCHLORIDE	ONDANSETRON HCL ORAL SOLN 4 MG/5ML	50250065052070	Generic

Approval Criteria

1 - Diagnosis of nausea and vomiting due to pregnancy (i.e., hyperemesis gravidarum) [10, 16]

AND

2 - History of failure, contraindication, or intolerance to at least one of the following: [A]

- doxylamine
- metoclopramide (Reglan)
- prochlorperazine (Compazine)
- promethazine (Phenergan)
- pyridoxine (Vitamin B6)

AND

3 - Patient has had at least a partial response to therapy at a dose within the quantity limit

3 . Background

Benefit/Coverage/Program Information
Quantity Limit These products are subject to a standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.

4 . Endnotes

A. Treatment of nausea and vomiting of pregnancy with vitamin B6 or vitamin B6 plus doxylamine is safe and effective and should be considered first-line pharmacotherapy (Level A Evidence). Treatment of nausea and vomiting of pregnancy with ginger has shown beneficial effects and can be considered as a nonpharmacologic option (Level B

Evidence). Several types of dopamine antagonists can be used for the treatment of nausea and vomiting of pregnancy such as promethazine, prochlorperazine, and metoclopramide. Antihistamines (such as dimenhydrinate and diphenhydramine) have been shown to be effective in controlling nausea and vomiting symptoms of pregnancy and are frequently used. Evidence is limited on the safety or efficacy of the 5-HT3 inhibitors (e.g. ondansetron) for nausea and vomiting of pregnancy. The ACOG recommends discussing the available data with patients as well as weighing the risks and benefits in women less than 10 weeks of gestation. Because of their limited data, they should not be advocated for first-line use until agents with established safety and efficacy have been tried and have failed. Treatment of severe nausea and vomiting of pregnancy or hyperemesis gravidarum with methylprednisolone may be efficacious in refractory cases; however, the risk profile of methylprednisolone suggests it should be a treatment of last resort (Level B Evidence). [16]

5 . References

1. Akynzeo prescribing information. Helsinn Therapeutics (U.S.), Inc. Iselin, NJ. February 2023.
2. Anzemet prescribing information. Validus Pharmaceuticals LLC. Parsippany, NJ. December 2023.
3. Emend prescribing information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. May 2022.
4. Granisetron prescribing information. Ascend Laboratories. Montvale, NJ. July 2022.
5. Marinol prescribing information. AbbVie Inc. North Chicago, IL. August 2017.
6. Sancuso prescribing information. Kyowa Kirin, Inc. Bedminster, NJ. July 2024.
7. Varubi prescribing information. TerSera Therapeutics LLC. Deerfield, IL. August 2020.
8. Zofran prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2020.
9. Zuplenz prescribing information. Fortovia Therapeutics, Inc. Raleigh, NC. May 2020.
10. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically. Available by subscription at: http://www.thomsonhc.com/. Accessed September 9, 2021.
11. Fauser AA, Russ W, Bischoff M. Oral dolasetron mesilate (MDL 73,147EF) for the control of emesis during fractionated total-body irradiation and high-dose cyclophosphamide in patients undergoing allogeneic bone marrow transplantation. Support Care Cancer. 1997 May;5(3):219-22.
12. Basch E, Prestrud AA, Hesketh PJ, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clinic Oncol. 2011;29(31):4189-98.
13. AHFS Drug Information website. Available at: https://online.lexi.com/lco/action/doc/retrieve/docid/250/413041. Accessed September 9, 2021.
14. Fujii Y, Tanaka H, Kawasaki T. Preoperative oral granisetron for the prevention of postoperative nausea and vomiting after breast surgery. Eur J Surg. 2001 Mar;167(3):184-7.
15. Fujii Y, Tanaka H, Kawasaki T. Prophylaxis with oral granisetron for the prevention of nausea and vomiting after laparoscopic cholecystectomy: a prospective randomized study. Arch Surg. 2001 Jan;136(1):101-4.

16. ACOG Practice Bulletin. Nausea and vomiting of pregnancy. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2018; 103(1):15-30.
17. Sustol prescribing information. Heron Therapeutics. San Diego, CA. May 2023.

6 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228352
Guideline Name	AntiGout Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Uloric (febuxostat)
Gout A xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable. Uloric is not recommended for the treatment of asymptomatic hyperuricemia.
Drug Name: Mitigare (colchicine) capsule
Prophylaxis of gout flares Indicated for prophylaxis of gout flares in adults. Limitation of Use: The safety and effectiveness of Mitigare for acute treatment of gout flares during prophylaxis has not been studied. Mitigare is not an analgesic medication and should not be used to treat pain from other causes.
Drug Name: Colcrys (colchicine) tablet
Prophylaxis of Gout Flares Indicated for the prophylaxis of gout flares. **Treatment of Gout Flares** Indicated for treatment of acute gout flares when taken at the first sign of a flare.

Familial Mediterranean Fever (FMF) Indicated in adults and children 4 years or older for treatment of FMF.

Drug Name: Allopurinol

Gout Indicated in: 1) the management of patients with signs and symptoms of primary or secondary gout (acute attacks, tophi, joint destruction, uric acid lithiasis, and/or nephropathy). 2) the management of patients with leukemia, lymphoma and malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels. Treatment with allopurinol should be discontinued when the potential for over production of uric acid is no longer present. 3) the management of patients with recurrent calcium oxalate calculi whose daily uric acid excretion exceeds 800 mg/day in male patients and 750 mg/day in female patients. Therapy in such patients should be carefully assessed initially and reassessed periodically to determine in each case that treatment is beneficial and that the benefits outweigh the risks.

2 . Criteria

Product Name:generic febuxostat, Uloric	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ULORIC	FEBUXOSTAT TAB 40 MG	68000030000320	Brand
ULORIC	FEBUXOSTAT TAB 80 MG	68000030000330	Brand
FEBUXOSTAT	FEBUXOSTAT TAB 40 MG	68000030000320	Generic
FEBUXOSTAT	FEBUXOSTAT TAB 80 MG	68000030000330	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to generic allopurinol

Product Name:Mitigare, Brand Colcrys	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
MITIGARE	COLCHICINE CAP 0.6 MG	68000020000120	Generic
COLCRYS	COLCHICINE TAB 0.6 MG	68000020000310	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 30 days supply within past 180 days, or intolerance to generic colchicine tablets

Product Name:Brand Allopurinol 200mg tablet	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ALLOPURINOL	ALLOPURINOL TAB 200 MG	68000010000307	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), or intolerance to generic allopurinol

3 . References

1. Uloric Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. April 2023.
2. Mitigare Prescribing Information. Specialty USA Inc. Columbus, OH. May 2024.
3. Colchicine Tablets Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. December 2021.
4. Allopurinol Prescribing Information. Camber Pharmaceuticals, Inc. Piscataway, NJ 08854. August 2023.

Prior Authorization Guideline

Guideline ID	GL-228797
Guideline Name	Antimalarial Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Qualaquin (quinine sulfate)
Malaria Indicated only for treatment of uncomplicated Plasmodium falciparum malaria. Quinine sulfate has been shown to be effective in geographical regions where resistance to chloroquine has been documented. Limitations of Use: 1) Not approved for patients with severe or complicated P. falciparum malaria. 2) Not approved for prevention of malaria. 3) Not indicated for the prevention or treatment of nocturnal leg cramps.

2 . Criteria

Product Name:Brand Qualaquin, Generic quinine sulfate	
Diagnosis	Nocturnal Leg Cramps*
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QUALAQUIN	QUININE SULFATE CAP 324 MG	13000060100119	Brand
QUININE SULFATE	QUININE SULFATE CAP 324 MG	13000060100119	Generic

Approval Criteria

1 - Requests for coverage when used solely for the treatment or prevention of nocturnal leg cramps are not authorized and will not be approved [1, C]

Notes	*Nocturnal leg cramp is an off-label use.

Product Name:Brand Qualaquin, Generic quinine sulfate	
Diagnosis	Malaria
Approval Length	7 days [1]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QUALAQUIN	QUININE SULFATE CAP 324 MG	13000060100119	Brand
QUININE SULFATE	QUININE SULFATE CAP 324 MG	13000060100119	Generic

Approval Criteria

1 - Diagnosis of uncomplicated malaria

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Treatment in areas of chloroquine-sensitive malaria [2-4, A]*

AND **2.1.2** Trial and failure, contraindication or intolerance to one of the following: • chloroquine • hydroxychloroquine **OR** **2.2** Treatment in areas of chloroquine-resistant malaria [2-4, B]*	
Notes	*Call the Malaria Hotline (770-488-7788) for additional information if n eeded.

3 . Endnotes

A. Areas of chloroquine-sensitive malaria include: Central America west of the Panama Canal, Haiti and the Dominican Republic. [2-4]
B. Areas of chloroquine-resistant malaria include: Southeast Asia, and all malarious regions except those specified as chloroquine-sensitive listed in Endnote A. [2-4]
C. Quinine is not approved for and should not be used for the prophylaxis or treatment of nocturnal leg cramps. Quinine may cause unpredictable serious and life-threatening hematologic reactions including thrombocytopenia and hemolytic-uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP) in addition to hypersensitivity reactions, QT prolongation, serious cardiac arrhythmias including torsades de pointes, and other serious adverse events requiring medical intervention and hospitalization. Chronic renal impairment associated with the development of TTP, and fatalities have also been reported. The risk associated with the use of quinine in the absence of evidence of its effectiveness for treatment or prevention of nocturnal leg cramps, outweighs any potential benefit in treating and/or preventing this benign, self-limiting condition. [1]

4 . References

1. Qualaquin Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. August 2019.
2. Center for Disease Control Traveler's Health - Yellow Book 2020 edition. Chapter 4: Infectious diseases related to travel - malaria. Available at:

https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/malaria. Accessed May 1, 2024.
3. Center for Disease Control. Guideline for treatment of malaria in the United States. Available at: http://www.cdc.gov/malaria/diagnosis_treatment/treatment.html. Accessed May 1, 2024.
4. Griffith KS, Lewis LS, Mali S, Parise ME. Treatment of malaria in the United States. A systematic review. JAMA. 2007;297(20):2264-77.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228354
Guideline Name	Apomorphine Products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Apokyn (apomorphine injection)
Parkinson's Disease Indicated for the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced Parkinson's disease. Apokyn has been studied as an adjunct to other medications.

2 . Criteria

Product Name:Brand Apokyn, Generic Apomorphine Hydrochloride Inj	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
APOKYN	APOMORPHINE HCL SOLN CARTRIDGE 30 MG/3ML	7320301010E220	Brand
APOMORPHINE HYDROCHLORIDE	APOMORPHINE HCL SOLN CARTRIDGE 30 MG/3ML	7320301010E220	Generic

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing intermittent OFF episodes

AND

3 - One of the following:

3.1 Patient is receiving drug in combination with carbidopa/levodopa at a maximally tolerated dose

OR

3.2 Patient has a contraindication or intolerance to carbidopa/levodopa

AND

4 - Trial and failure (of a minimum 30 day supply), contraindication or intolerance to two of the following: [A]

- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT Inhibitor (e.g., entacapone)

AND

5 - Both of the following:

5.1 Trial and failure (of a minimum 30 day supply), contraindication or intolerance to generic apomorphine (Applies to Brand Apokyn only)

AND

5.2 One of the following:

5.2.1 Trial and failure (of a minimum 30 day supply), contraindication or intolerance to Inbrija (levodopa) inhalation powder

OR

5.2.2 For continuation of prior therapy

AND

6 - Not used with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)

AND

7 - Prescribed by or in consultation with a neurologist

Product Name:Brand Apokyn, Generic Apomorphine Hydrochloride Inj	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
APOKYN	APOMORPHINE HCL SOLN CARTRIDGE 30 MG/3ML	7320301010E220	Brand
APOMORPHINE HYDROCHLORIDE	APOMORPHINE HCL SOLN CARTRIDGE 30 MG/3ML	7320301010E220	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Apokyn prescribing information. US WorldMeds, LLC. Louisville, KY. June 2022.
2. Obering CD, Chen JJ, Swope DM. Update on apomorphine for the rapid treatment of hypomobility ("off") episodes in Parkinson's disease. Pharmacotherapy. 2006;26(6):840-852.
3. Per clinical consult with neurologist, March 27, 2019.

Aqneursa (levacetylleucine)

Prior Authorization Guideline

Guideline ID	GL-233293
Guideline Name	Aqneursa (levacetylleucine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/21/2024
P&T Revision Date:	

1 . Indications

Drug Name: Aqneursa (levacetylleucine)
Niemann-Pick disease type C (NPC) Indicated for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing greater than or equal to 15kg.

2 . Criteria

Product Name:Aqneursa	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AQNEURSA	LEVACETYLLEUCINE FOR SUSP PACKET 1 GM	62000023003020	Brand

Approval Criteria

1 - Diagnosis of Niemann-Pick disease type C (NPC)

AND

2 - Diagnosis is confirmed by one of the following:

2.1 Genetically confirmed (deoxyribonucleic acid [DNA] sequence analysis) by mutations in both alleles of NPC1 or NPC2

OR

2.2 Mutation in only one allele of NPC1 or NPC2 plus either positive filipin staining or elevated cholestane triol/oxysterols (>2 x upper limit of normal)

AND

3 - Patient has at least one neurological symptom of the disease (e.g., hearing loss, vertical supranuclear gaze palsy, ataxia, dementia, dystonia, seizures, dysarthria, or dysphagia)

AND

4 - Patient weighs greater than or equal to 15kg

AND

5 - Requested drug will not be used in combination with Miplyffa (arimoclomol)

AND

6 - Prescribed by or in consultation with a specialist knowledgeable in the treatment of Niemann-Pick disease type C

Product Name:Aqneursa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AQNEURSA	LEVACETYLLEUCINE FOR SUSP PACKET 1 GM	62000023003020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., slowing of disease progression, improvement in neurological symptoms of the disease)

AND

2 - Requested drug will not be used in combination with Miplyffa (arimoclomol)

3 . References

1. Aqneursa Prescribing Information. IntraBio Inc. Austin TX 78701. September 2024.
2. Bremova-Ertl T, Ramaswami U, Brands M, et al. Trial of N-Acetyl-l-Leucine in Niemann-Pick Disease Type C. N Engl J Med. 2024 Feb 1;390(5):421-431. doi: 10.1056/NEJMoa2310151. PMID: 38294974.
3. FDA Review: Aqneursa. Food and Drug Administration Web Site. 2024. http://www.accessdata.fda.gov. Accessed November 4, 2024

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228356
Guideline Name	Arcalyst (rilonacept)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Arcalyst (rilonacept) injection
Cryopyrin-Associated Periodic Syndromes (CAPS) Indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and pediatric patients 12 years and older. **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)** Indicated for the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg. **Recurrent Pericarditis** Indicated for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

2 . Criteria

Product Name:Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ARCALYST	RILONACEPT FOR INJ 220 MG	66450060002120	Brand

Approval Criteria

1 - Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS) [A]

AND

2 - Prescribed by or in consultation with one of the following:

- Immunologist
- Allergist
- Dermatologist
- Rheumatologist
- Neurologist
- Specialist with expertise in the management of CAPS

AND

3 - The medication will not be used in combination with another biologic agent

Product Name:Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ARCALYST	RILONACEPT FOR INJ 220 MG	66450060002120	Brand

Approval Criteria

1 - Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidenced by one of the following:

- Improvement in rash, fever, joint pain, headache, or conjunctivitis
- Decreased number of disease flare days
- Normalization of inflammatory markers (C-reactive protein [CRP], erythrocyte sedimentation rate [ESR], serum amyloid A [SAA])
- Corticosteroid dose reduction
- Improvement in MD global score or active joint count

Product Name:Arcalyst	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ARCALYST	RILONACEPT FOR INJ 220 MG	66450060002120	Brand

Approval Criteria

1 - Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)

AND

2 - Patient weighs at least 10 kg

AND

3 - Patient is currently in remission (e.g., no fever, skin rash, and bone pain; no radiological evidence of active bone lesions; C-reactive protein [CRP] less than 5 mg/L)

Product Name:Arcalyst	
Diagnosis	Recurrent Pericarditis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ARCALYST	RILONACEPT FOR INJ 220 MG	66450060002120	Brand

Approval Criteria

1 - Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart [1, 4-5]

AND

2 - Prescribed by or in consultation with a cardiologist

AND

3 - Trial and failure, contraindication, or intolerance to at least one of the following [4-5]:

- nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen)
- colchicine
- corticosteroids (e.g., prednisone)

Product Name:Arcalyst	
Diagnosis	Recurrent Pericarditis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ARCALYST	RILONACEPT FOR INJ 220 MG	66450060002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Definitions

Definition	Description
CIAS1 gene:	Also known as cold-induced auto-inflammatory syndrome 1, is a gene responsible for the regulation of IL-1 production. Mutation(s) in this gene leads to CAPS. [2]
Chronic Infantile Neurologic Cutaneous and Articular Syndrome:	Also known as neonatal-Onset Multisystem Inflammation, is the most severe form of the CAPS. It is characterized by nearly continuous symptoms of inflammation presenting first during the neonatal period or early infancy with migratory and nonpruritic urticaria-like rash and fever. Other features of this disease include chronic aseptic meningitis, sensorineural hearing loss and ocular changes (conjunctivitis, optic nerve atrophy), and disabling arthropathy caused by overgrowth of the patella and epiphyses of the long bones. Approximately 20% of patients with this disease die before reaching adulthood. [2, 3]
Cryopyrin-Associated Periodic Syndromes (CAPS):	A group of rare, autosomal dominantly inherited auto-inflammatory conditions comprising of Familial-Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or also known as Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA), which are caused by the CIAS1 gene mutation and characterized by recurrent symptoms (urticaria-like skin lesions, fever chills, arthralgia, profuse sweating, sensorineural hearing/vision loss, and increased inflammation markers the blood).

	Approximately 300 people in the United States are affected by CAPS. [2, 3]
Familial Cold Autoinflammatory Syndrome:	The mildest form of CAPS, is characterized by cold-induced, daylong episodes of fever associated with rash, arthralgia, headaches and less frequently conjunctivitis, but without other signs of CNS inflammation. Symptoms usually begin during the first 6 months of life and are predominantly triggered by cold exposure. Duration of episodes usually is less than 24 hours. [2, 3]
Muckle-Wells Syndrome:	A subtype of CAPS, which is characterized by episodic attacks of inflammation associated with a generalized urticaria-like rash, fever, malise, arthralgia, and progressive hearing loss. Duration of symptoms usually lasts from 24-48 hours. [2, 3]

4 . Endnotes

A. CAPS refer to rare genetic syndromes generally caused by mutations in the NLRP-3 [Nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]). CAPS disorders are inherited in an autosomal dominant pattern with male and female offspring equally affected. Features common to all disorders include fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis. In most cases, inflammation in CAPS is associated with mutations in the NLRP-3 gene which encodes the protein cryopyrin, an important component of the inflammasome. Mutations in NLRP-3 result in an overactive inflammasome resulting in excessive release of activated IL-1β that drives inflammation. [1]

5 . References

1. Arcalyst Prescribing Information. Regeneron Pharmaceuticals. Zug, Switzerland. May 2021.
2. Aksentijevich I, Putnam CD, Remmers EF, et al. The clinical continuum of cryopyrinopathies: novel CIAS1 mutations in North American Patients and a new cryopyrin model. Arthritis Rheum. 2007; 56(4):1273-1285.
3. McDermott M, Aksentijevich I. The auto-inflammatory syndromes. Curr Opin Allergy Clin Immunol. 2002; 2:511-516.
4. Chiabrando JG, Bonaventura A, Vecchie A, et al. Management of acute and recurrent pericarditis. J Am Coll Cardiol. 2020;75(1):76–92.
5. Klein AL, Imazio M, Cremer P, et al. Phase 3 trial of interleukin-1 trap rilonacept in recurrent pericarditis. N Engl J Med 2021;384:31-41.

Prior Authorization Guideline

Guideline ID	GL-228358
Guideline Name	Arikayce (amikacin liposome inhalation suspension)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Arikayce (amikacin liposome inhalation suspension)
Mycobacterium avium complex Indicated in adults who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. As only limited clinical safety and effectiveness data for ARIKAYCE are currently available, reserve ARIKAYCE for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.

2 . Criteria

Product Name:Arikayce	
Diagnosis	Mycobacterium avium complex (MAC) lung disease

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ARIKAYCE	AMIKACIN SULFATE LIPOSOME INHAL SUSP 590 MG/8.4ML (BASE EQ)	07000010121830	Brand

Approval Criteria

1 - Diagnosis of Mycobacterium avium complex (MAC) lung disease

AND

2 - Requested drug will be used alongside a combination antibacterial drug regimen (e.g., clarithromycin, rifampin and ethambutol)

AND

3 - Both of the following:

3.1 Patient has received a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g., a macrolide, a rifamycin, ethambutol, etc.) before starting therapy with the requested drug

AND

3.2 Patient has not achieved at least two negative sputum cultures following this treatment regimen [1,2]

AND

4 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

3 . References

1. Arikayce Prescribing Information. Insmed, Bridgewater, NJ. February 2023.
2. Daley CL, Iaccarino JM, Lange C, et al. Treatment of nontuberculous mycobacterial pulmonary disease: an official ATS/ERS/ESCMID/IDSA clinical practice guideline. Eur Respir J. 2020;56(1):2000535.

Prior Authorization Guideline

Guideline ID	GL-228359
Guideline Name	Atopic Dermatitis Topical Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Eucrisa (crisaborole) ointment
Atopic Dermatitis Indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

2 . Criteria

Product Name:Eucrisa	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
EUCRISA	CRISABOROLE OINT 2%	90230025004220	Brand

Approval Criteria

1 - Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to one prescription strength topical corticosteroid (see Table 1 in Background section), unless the affected area is sensitive (i.e., face, axillae, groin). [2]

OR

2 - Trial and failure (of a minimum 30-day supply) or intolerance to one generic topical calcineurin inhibitor (e.g., tacrolimus ointment), unless the patient is not a candidate for therapy (e.g., immunocompromised) [3]

3 . Background

Clinical Practice Guidelines

Table 1. Relative Potencies of Topical Corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05

	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
	Dexamethasone	Cream	0.1

Lowest potency	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . References

1. Eucrisa Prescribing Information. Pfizer, Inc. New York, NY. April 2023.
2. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023; Epub ahead of print.
3. Protopic Prescribing Information. Leo Pharma Inc. Madison, NJ. February 2019.

Prior Authorization Guideline

Guideline ID	GL-233363
Guideline Name	Atypical Antipsychotics - PA, ST
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	3/22/1998
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Fanapt (iloperidone)
Schizophrenia Indicated for the treatment of adults with schizophrenia. When deciding among the alternative treatments available for this condition, the prescriber should consider the finding that Fanapt is associated with prolongation of the QTc interval. Prolongation of the QTc interval is associated in some other drugs with the ability to cause torsade de pointes-type arrhythmia, a potentially fatal polymorphic ventricular tachycardia which can result in sudden death. In many cases this would lead to the conclusion that other drugs should be tried first. Whether Fanapt will cause torsade de pointes or increase the rate of sudden death is not yet known. Patients must be titrated to an effective dose of Fanapt. Thus, control of symptoms may be delayed during the first 1 to 2 weeks of treatment compared to some other antipsychotic drugs that do not require a similar titration. Prescribers should be mindful of this delay when selecting an antipsychotic drug for the treatment of schizophrenia. **Bipolar I disorder** Indicated for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

Drug Name: Nuplazid (pimavanserin)
Parkinson's disease psychosis Indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.
Drug Name: Secuado (asenapine)
Schizophrenia Indicated for the treatment of adults with schizophrenia
Drug Name: Caplyta
Schizophrenia Indicated for the treatment of schizophrenia in adults **Bipolar Depression** Indicated for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate
Drug Name: Lybalvi
Schizophrenia Indicated for the treatment of schizophrenia in adults **Bipolar I disorder** Indicated for the acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate in adults with Bipolar I disorder. Indicated as maintenance monotherapy treatment in adults with Bipolar I disorder.
Drug Name: Saphris
Schizophrenia Indicated for the treatment of schizophrenia in adults **Bipolar I Disorder** Indicated for acute monotherapy of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age, indicated for adjunctive treatment to lithium or valproate in adults, and indicated for maintenance monotherapy treatment in adults
Drug Name: Invega Hafyera (paliperidone palmitate)
Schizophrenia Indicated for the treatment of schizophrenia in adults after they have been adequately treated with either a once-a-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA SUSTENNA) for at least four months, or an every-three-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA TRINZA) for at least one three-month cycle.
Drug Name: Erzofri (paliperidone palmitate)
Schizophrenia Indicated for the treatment of 1) Schizophrenia in adults, and 2) Schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.
Drug Name: Opipza (aripiprazole)

Schizophrenia Indicated for the treatment of schizophrenia in patients ages 13 years and older.

Major Depressive Disorder (MDD) Indicated for adjunctive treatment of major depressive disorder (MDD) in adults.

Autism Indicated for irritability associated with autistic disorder in pediatric patients 6 years and older.

Tourette's Syndrome Indicated for treatment of Tourette's disorder in pediatric patients 6 years and older.

2 . Criteria

Product Name:Nuplazid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUPLAZID	PIMAVANSERIN TARTRATE CAP 34 MG (BASE EQUIVALENT)	59400028200120	Brand
NUPLAZID	PIMAVANSERIN TARTRATE TAB 10 MG (BASE EQUIVALENT)	59400028200310	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Parkinson's disease

AND

1.2 Patient has at least one of the following:

- Hallucinations
- Delusions

OR

2 - For continuation of prior therapy

Product Name:Fanapt, Fanapt Pak, Secuado, Brand Saphris, Lybalvi	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
FANAPT	ILOPERIDONE TAB 1 MG	59070035000310	Brand
FANAPT	ILOPERIDONE TAB 2 MG	59070035000320	Brand
FANAPT	ILOPERIDONE TAB 4 MG	59070035000340	Brand
FANAPT	ILOPERIDONE TAB 6 MG	59070035000360	Brand
FANAPT	ILOPERIDONE TAB 8 MG	59070035000380	Brand
FANAPT	ILOPERIDONE TAB 10 MG	59070035000385	Brand
FANAPT	ILOPERIDONE TAB 12 MG	59070035000390	Brand
FANAPT TITRATION PACK	ILOPERIDONE TAB 1 MG & 2 MG & 4 MG & 6 MG TITRATRATION PAK	59070035006320	Brand
SECUADO	ASENAPINE TD PATCH 24 HR 3.8 MG/24HR	59155015008520	Brand
SECUADO	ASENAPINE TD PATCH 24 HR 5.7 MG/24HR	59155015008530	Brand
SECUADO	ASENAPINE TD PATCH 24 HR 7.6 MG/24HR	59155015008540	Brand
SAPHRIS	ASENAPINE MALEATE SL TAB 2.5 MG (BASE EQUIV)	59155015100710	Brand
SAPHRIS	ASENAPINE MALEATE SL TAB 5 MG (BASE EQUIV)	59155015100720	Brand
SAPHRIS	ASENAPINE MALEATE SL TAB 10 MG (BASE EQUIV)	59155015100730	Brand
LYBALVI	OLANZAPINE-SAMIDORPHAN L-MALATE TAB 5-10 MG	62994802500310	Brand
LYBALVI	OLANZAPINE-SAMIDORPHAN L-MALATE TAB 10-10 MG	62994802500320	Brand
LYBALVI	OLANZAPINE-SAMIDORPHAN L-MALATE TAB 15-10 MG	62994802500330	Brand
LYBALVI	OLANZAPINE-SAMIDORPHAN L-MALATE TAB 20-10 MG	62994802500340	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:

- aripiprazole
- olanzapine
- quetiapine IR/ER
- risperidone
- clozapine
- ziprasidone
- paliperidone
- asenapine

OR

2 - For continuation of prior therapy

Product Name:Invega Hafyera	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
INVEGA HAFYERA	PALIPERIDONE PALMITATE ER SUSP PREF SYR 1,092 MG/3.5ML	5907005010E670	Brand
INVEGA HAFYERA	PALIPERIDONE PALMITATE ER SUSP PREF SYR 1,560 MG/5ML	5907005010E675	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial of one of the following:

- Invega Sustenna for at least 4 months
- Invega Trinza for at least one 3-month cycle

OR

2 - For continuation of prior therapy

Product Name:Caplyta	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
CAPLYTA	LUMATEPERONE TOSYLATE CAP 42 MG	59400022400120	Brand
CAPLYTA	LUMATEPERONE TOSYLATE CAP 10.5 MG	59400022400110	Brand
CAPLYTA	LUMATEPERONE TOSYLATE CAP 21 MG	59400022400115	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Schizophrenia

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:

- aripiprazole
- olanzapine
- quetiapine IR/ER
- risperidone
- clozapine
- ziprasidone
- paliperidone
- asenapine

OR

2 - BOTH of the following:

- Patient has a diagnosis of Bipolar Depression
- Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to quetiapine IR/ER

OR

3 - For continuation of prior therapy

Product Name:Erzofri	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ERZOFRI	PALIPERIDONE PALMITATE ER SUSP PREF SYR 39 MG/0.25ML	5907005010E626	Brand
ERZOFRI	PALIPERIDONE PALMITATE ER SUSP PREF SYR 78 MG/0.5ML	5907005010E629	Brand
ERZOFRI	PALIPERIDONE PALMITATE ER SUSP PREF SYR 117 MG/0.75ML	5907005010E632	Brand
ERZOFRI	PALIPERIDONE PALMITATE ER SUSP PREF SYR 156 MG/ML	5907005010E635	Brand
ERZOFRI	PALIPERIDONE PALMITATE ER SUSP PREF SYR 234 MG/1.5ML	5907005010E638	Brand
ERZOFRI	PALIPERIDONE PALMITATE ER SUSP PREF SYR 351 MG/2.25ML	5907005010E639	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial of one of the following:

- Invega Sustenna
- Invega Trinza

OR

2 - For continuation of prior therapy

Product Name:Opipza	
Diagnosis	Schizophrenia
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
OPIPZA	ARIPIPRAZOLE ORAL FILM 2 MG	59250015008205	Brand
OPIPZA	ARIPIPRAZOLE ORAL FILM 5 MG	59250015008210	Brand
OPIPZA	ARIPIPRAZOLE ORAL FILM 10 MG	59250015008220	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Schizophrenia

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:

- aripiprazole
- olanzapine
- quetiapine IR/ER
- risperidone
- clozapine
- ziprasidone
- paliperidone
- asenapine

OR

2 - For continuation of prior therapy

Product Name:Opipza	
Diagnosis	Major Depressive Disorder (MDD)
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
OPIPZA	ARIPIPRAZOLE ORAL FILM 2 MG	59250015008205	Brand
OPIPZA	ARIPIPRAZOLE ORAL FILM 5 MG	59250015008210	Brand
OPIPZA	ARIPIPRAZOLE ORAL FILM 10 MG	59250015008220	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Major Depressive Disorder (MDD)

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to both of the following: :

- aripiprazole
- quetiapine IR/ER

OR

2 - For continuation of prior therapy

Product Name:Opipza	
Diagnosis	Autism
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
OPIPZA	ARIPIPRAZOLE ORAL FILM 2 MG	59250015008205	Brand
OPIPZA	ARIPIPRAZOLE ORAL FILM 5 MG	59250015008210	Brand
OPIPZA	ARIPIPRAZOLE ORAL FILM 10 MG	59250015008220	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of irritability associated with autistic disorder

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication (e.g., age), or intolerance to both of the following: :

- aripiprazole

- risperidone

OR

2 - For continuation of prior therapy

Product Name:Opipza	
Diagnosis	Tourette's Syndrome
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
OPIPZA	ARIPIPRAZOLE ORAL FILM 2 MG	59250015008205	Brand
OPIPZA	ARIPIPRAZOLE ORAL FILM 5 MG	59250015008210	Brand
OPIPZA	ARIPIPRAZOLE ORAL FILM 10 MG	59250015008220	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Tourette's Syndrome

AND

1.2 Trial and failure (of a minimum 30 day supply), or intolerance to aripiprazole

OR

2 - For continuation of prior therapy

3 . References

1. Fanapt prescribing information. Vanda Pharmaceuticals, Inc. Washington, D.C. January 2016.

2. Nuplazid prescribing information. Acadia Pharmaceuticals Inc. San Diego, CA. May 2019.
3. Secuado prescribing information. Hisamitsu Pharmaceutical Co., Inc. Japan Saga Tosu. October 2019.
4. Caplyta prescribing information. Intra-Cellular Therapies, Inc. New York, NY. December 2021.
5. Saphris prescribing information. Allergan USA, Inc. Irvine, CA. February 2017.
6. Invega Hafyera prescribing information. Janssen Pharmaceuticals, Inc. Titusville, NJ. September 2021.
7. Lybalvi prescribing information. Alkermes, Inc. Waltham, MA. May 2021.
8. Erzofri prescribing information. Shandong Luye Pharmaceutical Co., Ltd. Yantai, Shandong Province, China. July 2024.
9. Opipza prescribing information. Xiamen LP Pharmaceutical Co., Ltd. Fujian, China. July 2024.
10. Abilify prescribing information. Otsuka America Pharmaceutical, Inc. Rockville, MD. November 2022.
11. Saphris prescribing information. Schering Corporation. Kenilworth, NJ. July 2009.
12. Geodon prescribing information. Pfizer Inc. New York, NY. January 2022.
13. Risperdal prescribing information. Janssen Pharmaceuticals, Inc. Titusville, NJ. March 2022.
14. Seroquel XR prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. January 2022.
15. Seroquel prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. January 2022.
16. Zyprexa prescribing information. Lilly USA, LLC. Indianapolis, IN. October 2019
17. Clozaril prescribing information. HLS Therapeutics (USA), Inc. Rosemont, PA. September 2024.
18. Invega prescribing information. Janssen Pharmaceuticals, Inc. Titusville, NJ. December 2021.

4 . Revision History

Date	Notes
3/4/2025	Quartz Comm/EHB copied to mirrow Optum standard/EHB

Prior Authorization Guideline

Guideline ID	GL-229153
Guideline Name	Augtyro (repotrectinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/15/2024
P&T Revision Date:	12/18/2024

1 . Indications

Drug Name: Augtyro (repotrectinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC). **Solid Tumors** Indicated for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that: 1) have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, 2) are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and 3) have progressed following treatment or have no satisfactory alternative therapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name:Augtyro	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AUGTYRO	REPOTRECTINIB CAP 40 MG	21533865000120	Brand
AUGTYRO	REPOTRECTINIB CAP 160 MG	21533865000130	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Patient has ROS1 rearrangement positive tumor(s) [A]

Product Name:Augtyro	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AUGTYRO	REPOTRECTINIB CAP 40 MG	21533865000120	Brand
AUGTYRO	REPOTRECTINIB CAP 160 MG	21533865000130	Brand

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Disease has neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1) [B]

AND

3 - Patient is 12 years of age or older

AND

4 - Disease is one of the following:

- Locally advanced
- Metastatic
- Unresectable (including cases where surgical resection is likely to result in severe morbidity)

AND

5 - One of the following:

- Disease has progressed following previous treatment (e.g., radiation therapy, systemic therapy, tyrosine kinase inhibitor [TKI])
- Disease has no satisfactory alternative treatments

Product Name:Augtyro	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AUGTYRO	REPOTRECTINIB CAP 40 MG	21533865000120	Brand
AUGTYRO	REPOTRECTINIB CAP 160 MG	21533865000130	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. An FDA-approved test to detect ROS1 rearrangements for selecting patients for treatment with AUGTYRO is not currently available. [1]
B. An FDA approved test to detect NTRK1/2/3 rearrangements for selecting patients for treatment with Augtyro is not currently available. [1]

4 . References

1. Augtyro Prescribing Information. Bristol-Myers Squibb Company. Princeton, NJ. June 2024.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228767
Guideline Name	Austedo (deutetrabenazine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Austedo (deutetrabenazine)
Chorea associated with Huntington's disease Indicated for the treatment of chorea associated with Huntington's disease in adults. **Tardive Dyskinesia** Indicated for tardive dyskinesia in adults.
Drug Name: Austedo XR (deutetrabenazine)
Chorea associated with Huntington's disease Indicated for the treatment of chorea associated with Huntington's disease in adults. **Tardive Dyskinesia** Indicated for tardive dyskinesia in adults.

2 . Criteria

Product Name:Austedo, Austedo XR	
Diagnosis	Chorea associated with Huntington’s disease
Approval Length	3 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AUSTEDO	DEUTETRABENAZINE TAB 6 MG	62380030000310	Brand
AUSTEDO	DEUTETRABENAZINE TAB 9 MG	62380030000320	Brand
AUSTEDO	DEUTETRABENAZINE TAB 12 MG	62380030000330	Brand
AUSTEDO PATIENT TITRATION KIT	DEUTETRABENAZINE TAB TITRATION PACK 6 MG & 9 MG & 12 MG	6238003000B720	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 6 MG	62380030007510	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 12 MG	62380030007520	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 24 MG	62380030007530	Brand
AUSTEDO XR PATIENT TITRATION KIT	DEUTETRABENAZINE TAB ER TITRATION PACK 6 MG & 12 MG & 24 MG	6238003000C120	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 30 MG	62380030007535	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 36 MG	62380030007540	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 42 MG	62380030007545	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 48 MG	62380030007550	Brand
AUSTEDO XR PATIENT TITRATION KIT	DEUTETRABENAZINE TAB ER TITRATION PACK 12 & 18 & 24 & 30 MG	6238003000C140	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 18 MG	62380030007525	Brand

Approval Criteria

1 - Diagnosis of chorea associated with Huntington's disease [1, 3, 4]

AND

2 - Prescribed by or in consultation with a neurologist [1, B]

Product Name:Austedo, Austedo XR	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AUSTEDO	DEUTETRABENAZINE TAB 6 MG	62380030000310	Brand
AUSTEDO	DEUTETRABENAZINE TAB 9 MG	62380030000320	Brand
AUSTEDO	DEUTETRABENAZINE TAB 12 MG	62380030000330	Brand
AUSTEDO PATIENT TITRATION KIT	DEUTETRABENAZINE TAB TITRATION PACK 6 MG & 9 MG & 12 MG	6238003000B720	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 6 MG	62380030007510	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 12 MG	62380030007520	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 24 MG	62380030007530	Brand
AUSTEDO XR PATIENT TITRATION KIT	DEUTETRABENAZINE TAB ER TITRATION PACK 6 MG & 12 MG & 24 MG	6238003000C120	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 30 MG	62380030007535	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 36 MG	62380030007540	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 42 MG	62380030007545	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 48 MG	62380030007550	Brand

AUSTEDO XR PATIENT TITRATION KIT	DEUTETRABENAZINE TAB ER TITRATION PACK 12 & 18 & 24 & 30 MG	6238003000C140	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 18 MG	62380030007525	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy [1]

Product Name:Austedo, Austedo XR	
Diagnosis	Tardive Dyskinesia
Approval Length	3 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AUSTEDO	DEUTETRABENAZINE TAB 6 MG	62380030000310	Brand
AUSTEDO	DEUTETRABENAZINE TAB 9 MG	62380030000320	Brand
AUSTEDO	DEUTETRABENAZINE TAB 12 MG	62380030000330	Brand
AUSTEDO PATIENT TITRATION KIT	DEUTETRABENAZINE TAB TITRATION PACK 6 MG & 9 MG & 12 MG	6238003000B720	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 6 MG	62380030007510	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 12 MG	62380030007520	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 24 MG	62380030007530	Brand
AUSTEDO XR PATIENT TITRATION KIT	DEUTETRABENAZINE TAB ER TITRATION PACK 6 MG & 12 MG & 24 MG	6238003000C120	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 30 MG	62380030007535	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 36 MG	62380030007540	Brand

AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 42 MG	62380030007545	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 48 MG	62380030007550	Brand
AUSTEDO XR PATIENT TITRATION KIT	DEUTETRABENAZINE TAB ER TITRATION PACK 12 & 18 & 24 & 30 MG	6238003000C140	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 18 MG	62380030007525	Brand

Approval Criteria

1 - Diagnosis of tardive dyskinesia [1, C]

AND

2 - Disease severity is one of the following:

- Moderate
- Severe

AND

3 - One of the following [7, D]:

3.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

3.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

4 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name:Austedo, Austedo XR	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AUSTEDO	DEUTETRABENAZINE TAB 6 MG	62380030000310	Brand
AUSTEDO	DEUTETRABENAZINE TAB 9 MG	62380030000320	Brand
AUSTEDO	DEUTETRABENAZINE TAB 12 MG	62380030000330	Brand
AUSTEDO PATIENT TITRATION KIT	DEUTETRABENAZINE TAB TITRATION PACK 6 MG & 9 MG & 12 MG	6238003000B720	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 6 MG	62380030007510	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 12 MG	62380030007520	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 24 MG	62380030007530	Brand
AUSTEDO XR PATIENT TITRATION KIT	DEUTETRABENAZINE TAB ER TITRATION PACK 6 MG & 12 MG & 24 MG	6238003000C120	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 30 MG	62380030007535	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 36 MG	62380030007540	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 42 MG	62380030007545	Brand
AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 48 MG	62380030007550	Brand
AUSTEDO XR PATIENT TITRATION KIT	DEUTETRABENAZINE TAB ER TITRATION PACK 12 & 18 & 24 & 30 MG	6238003000C140	Brand

AUSTEDO XR	DEUTETRABENAZINE TAB ER 24HR 18 MG	62380030007525	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy [1]

3 . Endnotes

A. Authorization period is based on the pivotal study duration of 12 weeks. [1, 5, 6]
B. Ensures the requirement for proper diagnosing and quantifying an adequate chorea score (total maximal chorea score of greater than or equal to 10 (moderate to severe chorea) from the subscale of the Unified Huntington's Disease Rating Scale (UHDRS). [1, 2]
C. Patients were included in the pivotal randomized, double-blind, placebo-controlled trial of Austedo if they had moderate to severe tardive dyskinesia as determined by clinical observation (qualitative assessment). [6]
D. Verified with consultant for a previous medication (Ingrezza [valbenazine]) that dose reduction, tapering, or discontinuation of the offending medication is considered first-line treatment for tardive dyskinesia. [8]

4 . References

1. Austedo Prescribing Information. Teva Pharmaceuticals USA, Inc. Parsippany, PA. May 2024.
2. Armstrong MJ, Miyasaki JM. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2012 August.
3. Claassen DO, Carroll B, De Boer LM, et al. Indirect tolerability comparison of deutetrabenazine and tetrabenazine for Huntington disease. J Clin Mov Disord. 2017. 4:3.
4. Geschwind MD, Paras N. Deutetrabenazine for treatment of chorea in Huntington disease. JAMA. 2016;316(1):33-34.
5. Huntington Study Group. Effect of deutetrabenazine on chorea among patients with Huntington disease. JAMA. 2016;316(1):40-50.
6. Fernandez HH, Factor SA, Hauser RA, et al. Randomized controlled trial of deutetrabenazine for tardive dyskinesia: The ARM-TD study. Neurology. 2017;88(21):2003-10.
7. Waln O, Jankovic J: An update on tardive dyskinesia: from phenomenology treatment. Tremor Other Hyperkinet Mov (N Y) 2013; 3: tre-03-161-4138-1.
8. Per clinical consult with psychiatrist regarding Ingrezza (valbenazine), June 9, 2017.

9. Austedo XR Prescribing Information. Teva Neuroscience, Inc. Parsippany, NJ. May 2024.

Prior Authorization Guideline

Guideline ID	GL-228362
Guideline Name	Ayvakit (avapritinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ayvakit (avapritinib)
Gastrointestinal Stromal Tumor (GIST) Indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. **Advanced Systemic Mastocytosis (AdvSM)** Indicated for the treatment of adult patients with advanced systemic mastocytosis (AdvSM). AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL). Limitations of Use: Ayvakit is not recommended for the treatment of patients with AdvSM with platelet counts of less than 50 × 10 /L. **Indolent Systemic Mastocytosis (ISM)** Indicated for the treatment of adult patients with indolent systemic mastocytosis (ISM). Limitations of Use: Ayvakit is not recommended for the treatment of patients with ISM with platelet counts of less than 50 × 10^9/L.

2 . Criteria

Product Name:Ayvakit	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AYVAKIT	AVAPRITINIB TAB 100 MG	21490009000320	Brand
AYVAKIT	AVAPRITINIB TAB 200 MG	21490009000330	Brand
AYVAKIT	AVAPRITINIB TAB 300 MG	21490009000340	Brand
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand
AYVAKIT	AVAPRITINIB TAB 50 MG	21490009000315	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Disease is ONE of the following:

- Unresectable
- Metastatic

AND

3 - Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations

Product Name:Ayvakit	
Diagnosis	Advanced Systemic Mastocytosis (AdvSM)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AYVAKIT	AVAPRITINIB TAB 100 MG	21490009000320	Brand
AYVAKIT	AVAPRITINIB TAB 200 MG	21490009000330	Brand
AYVAKIT	AVAPRITINIB TAB 300 MG	21490009000340	Brand
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand
AYVAKIT	AVAPRITINIB TAB 50 MG	21490009000315	Brand

Approval Criteria

1 - Diagnosis of advanced systemic mastocytosis (AdvSM)

AND

2 - Patient has one of the following:

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with an associated hematological neoplasm (SM-AHN)
- Mast cell leukemia (MCL)

AND

3 - Platelet count is greater than 50 x 10^9/L

Product Name:Ayvakit	
Diagnosis	Gastrointestinal Stromal Tumor (GIST), Advanced Systemic Mastocytosis (AdvSM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AYVAKIT	AVAPRITINIB TAB 100 MG	21490009000320	Brand
AYVAKIT	AVAPRITINIB TAB 200 MG	21490009000330	Brand
AYVAKIT	AVAPRITINIB TAB 300 MG	21490009000340	Brand
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand
AYVAKIT	AVAPRITINIB TAB 50 MG	21490009000315	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Ayvakit 25 mg	
Diagnosis	Indolent Systemic Mastocytosis (ISM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand

Approval Criteria

1 - Diagnosis of indolent systemic mastocytosis (ISM)

AND

2 - Platelet count is greater than 50 x 10^9/L

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Ayvakit 25 mg	
Diagnosis	Indolent Systemic Mastocytosis (ISM)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AYVAKIT	AVAPRITINIB TAB 100 MG	21490009000320	Brand
AYVAKIT	AVAPRITINIB TAB 200 MG	21490009000330	Brand
AYVAKIT	AVAPRITINIB TAB 300 MG	21490009000340	Brand
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand
AYVAKIT	AVAPRITINIB TAB 50 MG	21490009000315	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	If patient meets criteria above, please approve at GPI-14

3 . References

1. Ayvakit Prescribing Information. Blueprint Medicines Corporation. Cambridge, MA. May 2023.

Prior Authorization Guideline

Guideline ID	GL-228361
Guideline Name	Ayvakit (avapritinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ayvakit (avapritinib)
Gastrointestinal Stromal Tumor (GIST) Indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. **Advanced Systemic Mastocytosis (AdvSM)** Indicated for the treatment of adult patients with advanced systemic mastocytosis (AdvSM). AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL). Limitations of Use: Ayvakit is not recommended for the treatment of patients with AdvSM with platelet counts of less than 50 × 10 /L. **Indolent Systemic Mastocytosis (ISM)** Indicated for the treatment of adult patients with indolent systemic mastocytosis (ISM). Limitations of Use: Ayvakit is not recommended for the treatment of patients with ISM with platelet counts of less than 50 × 10^9/L.

2 . Criteria

Product Name:Ayvakit	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AYVAKIT	AVAPRITINIB TAB 100 MG	21490009000320	Brand
AYVAKIT	AVAPRITINIB TAB 200 MG	21490009000330	Brand
AYVAKIT	AVAPRITINIB TAB 300 MG	21490009000340	Brand
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand
AYVAKIT	AVAPRITINIB TAB 50 MG	21490009000315	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Disease is ONE of the following:

- Unresectable
- Metastatic

AND

3 - Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations

Product Name:Ayvakit	
Diagnosis	Advanced Systemic Mastocytosis (AdvSM)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AYVAKIT	AVAPRITINIB TAB 100 MG	21490009000320	Brand
AYVAKIT	AVAPRITINIB TAB 200 MG	21490009000330	Brand
AYVAKIT	AVAPRITINIB TAB 300 MG	21490009000340	Brand
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand
AYVAKIT	AVAPRITINIB TAB 50 MG	21490009000315	Brand

Approval Criteria

1 - Diagnosis of advanced systemic mastocytosis (AdvSM)

AND

2 - Patient has one of the following:

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with an associated hematological neoplasm (SM-AHN)
- Mast cell leukemia (MCL)

AND

3 - Platelet count is greater than 50 x 10^9/L

Product Name:Ayvakit	
Diagnosis	Gastrointestinal Stromal Tumor (GIST), Advanced Systemic Mastocytosis (AdvSM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AYVAKIT	AVAPRITINIB TAB 100 MG	21490009000320	Brand
AYVAKIT	AVAPRITINIB TAB 200 MG	21490009000330	Brand
AYVAKIT	AVAPRITINIB TAB 300 MG	21490009000340	Brand
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand
AYVAKIT	AVAPRITINIB TAB 50 MG	21490009000315	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Ayvakit 25 mg	
Diagnosis	Indolent Systemic Mastocytosis (ISM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand

Approval Criteria

1 - Diagnosis of indolent systemic mastocytosis (ISM)

AND

2 - Platelet count is greater than 50 x 10^9/L

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Ayvakit 25 mg	
Diagnosis	Indolent Systemic Mastocytosis (ISM)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AYVAKIT	AVAPRITINIB TAB 100 MG	21490009000320	Brand
AYVAKIT	AVAPRITINIB TAB 200 MG	21490009000330	Brand
AYVAKIT	AVAPRITINIB TAB 300 MG	21490009000340	Brand
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand
AYVAKIT	AVAPRITINIB TAB 50 MG	21490009000315	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	If patient meets criteria above, please approve at GPI-14

3 . References

1. Ayvakit Prescribing Information. Blueprint Medicines Corporation. Cambridge, MA. May 2023.

Prior Authorization Guideline

Guideline ID	GL-228798
Guideline Name	Azole Antifungals - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cresemba (isavuconazonium sulfate) capsules
Invasive Aspergillosis and Invasive Mucormycosis Indicated for adult and pediatric patients 6 years of age and older who weight 16 kilograms (kg) and greater for the treatment of invasive mucormycosis and invasive aspergillosis. Specimens for fungal culture and other relevant laboratory studies (including histopathology) to isolate and identify causative organism(s) should be obtained prior to initiating antifungal therapy. Therapy may be instituted before the results of the cultures and other laboratory studies are known. However, once these results become available, antifungal therapy should be adjusted accordingly.
Drug Name: Noxafil (posaconazole) tablets
Prophylaxis of Aspergillus infection Indicated for prophylaxis of invasive Aspergillus infections in adult and pediatric patients 2 years of age and older who weigh greater than 40 kg, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy. **Prophylaxis of Candida infection** Indicated for prophylaxis of invasive Candida infections in adult and pediatric patients 2 years of age and older who weigh greater than 40kg, who are at

high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Treatment of Invasive Aspergillosis Indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older.

Drug Name: Noxafil (posaconazole) oral suspension

Prophylaxis of Aspergillus infection Indicated for prophylaxis of invasive Aspergillus infections in patients 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Prophylaxis of Candida infection Indicated for prophylaxis of invasive Candida infections in patients 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Oropharyngeal candidiasis Indicated for treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults and pediatric patients 13 years of age and older.

Drug Name: Noxafil PowderMix (posaconazole) for delayed-release oral suspension

Prophylaxis of Invasive Aspergillus and Candida Infections Indicated for the prophylaxis of invasive Aspergillus and Candida infections in pediatric patients 2 years of age and older who weigh 40 kg or less, who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Drug Name: Sporanox (itraconazole) capsules

Blastomycosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary

Histoplasmosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis

Aspergillosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy

Onychomycosis of the toenail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (Tinea unguium)

Onychomycosis of the fingernail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)

Drug Name: Sporanox Pulse Pak (itraconazole)

Onychomycosis of the fingernail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)

Drug Name: Sporanox (itraconazole) oral solution

Oropharyngeal and esophageal candidiasis Indicated for the treatment of oropharyngeal and esophageal candidiasis.

Drug Name: Tolsura (itraconazole) capsules

Blastomycosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary.

Histoplasmosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis.

Aspergillosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy.

Drug Name: Vfend (voriconazole) oral suspension, Vfend (voriconazole) tablets

Invasive Aspergillosis Indicated in adults and pediatric patients (2 years of age and older) for the treatment of invasive aspergillosis (IA). In clinical trials, the majority of isolates recovered were Aspergillus fumigatus. There was a small number of cases of culture-proven disease due to species of Aspergillus other than A. fumigatus.

Candidemia in Non-neutropenic Patients and Other Deep Tissue Candida Infections Indicated in adults and pediatric patients (2 years of age and older) for the treatment of candidemia in non-neutropenic patients and the following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds.

Esophageal Candidiasis Indicated in adults and pediatric patients (2 years of age and older) for the treatment of esophageal candidiasis (EC) in adults and pediatric patients 2 years of age and older.

Scedosporiosis and Fusariosis Indicated for the treatment of serious fungal infections caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) and Fusarium spp. including Fusarium solani, in adults and pediatric patients (2 years of age and older) intolerant of, or refractory to, other therapy.

2 . Criteria

Product Name:Cresemba oral capsule	
Approval Length	6 Months [17, B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CRESEMBA	ISAVUCONAZONIUM SULFATE CAP 186 MG (ISAVUCONAZOLE 100 MG)	11407030100120	Brand
CRESEMBA	ISAVUCONAZONIUM SULFATE CAP 74.5 MG (ISAVUCONAZOLE 40 MG)	11407030100105	Brand

Approval Criteria

1 - Diagnosis of one of the following fungal infections: [17]

- Invasive aspergillosis
- Invasive mucormycosis

AND

2 - Both of the following:

- Patient is 6 years of age or older
- Patient weighs 16 kilograms or greater

Product Name:Brand Sporanox capsules or generic itraconazole capsules	
Diagnosis	Systemic and topical fungal infections
Approval Length	6 months [5, 10-12, B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

SPORANOX	ITRACONAZOLE CAP 100 MG	11407035000120	Brand
ITRACONAZOLE	ITRACONAZOLE CAP 100 MG	11407035000120	Generic

Approval Criteria

1 - Diagnosis of a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis)

OR

2 - All of the following:

2.1 One of the following diagnoses:

- Tinea corporis (ring worm)
- Tinea cruris (jock itch)
- Tinea pedis (athlete's foot)
- Tinea capitis (scalp ringworm)
- Pityriasus versicolor

AND

2.2 One of the following:

2.2.1 The tinea infection is resistant to topical antifungal treatment

OR

2.2.2 Trial and failure, contraindication, or intolerance to oral terbinafine [3]

Product Name:Brand Sporanox capsules, generic itraconazole capsules, or Sporanox Pulse Pak	
Diagnosis	Fingernail Onychomycosis
Approval Length	1 Month [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPORANOX	ITRACONAZOLE CAP 100 MG	11407035000120	Brand
ITRACONAZOLE	ITRACONAZOLE CAP 100 MG	11407035000120	Generic
SPORANOX PULSEPAK	ITRACONAZOLE CAP 100 MG	11407035000120	Brand

Approval Criteria

1 - Diagnosis of fingernail onychomycosis as confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Fungal culture
- Nail biopsy

AND

2 - The patient's condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, wearing shoes, or appropriately manicuring nails) [4]

AND

3 - Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine

Product Name:Brand Sporanox capsules or generic itraconazole capsules	
Diagnosis	Toenail Onychomycosis
Approval Length	3 Month [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPORANOX	ITRACONAZOLE CAP 100 MG	11407035000120	Brand
ITRACONAZOLE	ITRACONAZOLE CAP 100 MG	11407035000120	Generic

Approval Criteria

1 - Diagnosis of toenail onychomycosis as confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Fungal culture
- Nail biopsy

AND

2 - The patient's condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, walking, standing, wearing shoes, or appropriately manicuring nails) [4]

AND

3 - Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine

Product Name:Brand Sporanox oral solution or generic itraconazole oral solution	
Diagnosis	Candidiasis (esophageal or oropharyngeal)
Approval Length	1 month [E, F]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPORANOX	ITRACONAZOLE ORAL SOLN 10 MG/ML	11407035002020	Brand
ITRACONAZOLE	ITRACONAZOLE ORAL SOLN 10 MG/ML	11407035002020	Generic

Approval Criteria

1 - One of the following:

1.1 Diagnosis of esophageal candidiasis

OR

1.2 Diagnosis of oropharyngeal candidiasis (OPC)

AND

2 - One of the following:

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

Product Name:Tolsura	
Approval Length	6 months [5, 10-12, B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TOLSURA	ITRACONAZOLE CAP 65 MG	11407035000113	Brand

Approval Criteria

1 - Diagnosis of one of the following fungal infections:

- Blastomycosis
- Histoplasmosis
- Aspergillosis

AND

2 - Trial and failure or intolerance to generic itraconazole capsules

Product Name:Brand Noxafil oral suspension or generic posaconazole oral solution	
Diagnosis	Oropharyngeal Candidiasis
Approval Length	1 Month [E]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Brand
POSACONAZOLE	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Generic

Approval Criteria

1 - Diagnosis of oropharyngeal candidiasis (OPC)

AND

2 - Patient is 13 years of age and older

AND

3 - One of the following:

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

Product Name:Brand Noxafil oral suspension or generic posaconazole oral solution	
Diagnosis	Oropharyngeal Candidiasis
Approval Length	1 Month [E]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Brand
POSACONAZOLE	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Generic

Approval Criteria

1 - Diagnosis of oropharyngeal candidiasis (OPC)

AND

2 - Patient is 13 years of age and older

AND

3 - Submission of medical records (e.g., chart notes) or paid claims documenting one of the following:

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

Product Name:Brand Noxafil oral tablet, generic posaconazole oral tablet, Brand Noxafil oral suspension, generic posaconazole oral suspension, Noxafil PowderMix	
Diagnosis	Prophylaxis of systemic fungal infections
Approval Length	6 Months [B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Brand
POSACONAZOLE DR	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic
NOXAFIL	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Brand
NOXAFIL	POSACONAZOLE FOR DELAYED RELEASE SUSP PACKET 300 MG	11407060003020	Brand
POSACONAZOLE	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Generic

Approval Criteria

1 - Used as prophylaxis of invasive fungal infections caused by one of the following:

- Aspergillus
- Candida

AND

2 - One of the following:

2.1 For Noxafil (posaconazole) oral tablet, both of the following:

- Patient is 2 years of age and older
- Patient weighs greater than 40 kg

OR

2.2 For Noxafil oral suspension, patient is 13 years of age and older

OR

2.3 For Noxafil PowderMix, both of the following:

- Patient is 2 years of age and older
- Patient weighs 40 kg or less

AND

3 - One of the following:

3.1 Patient is at high risk of infections due to severe immunosuppression from one of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy

OR

3.2 Patient has a prior fungal infection requiring secondary prophylaxis [15, G]

Product Name:Brand Noxafil oral tablet, generic posaconazole oral tablet, Brand Noxafil oral suspension, generic posaconazole oral suspension, Noxafil PowderMix	
Diagnosis	Prophylaxis of systemic fungal infections

Approval Length	6 Months [B-D]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Brand
POSACONAZOLE DR	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic
NOXAFIL	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Brand
NOXAFIL	POSACONAZOLE FOR DELAYED RELEASE SUSP PACKET 300 MG	11407060003020	Brand
POSACONAZOLE	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Generic

Approval Criteria

1 - Used as prophylaxis of invasive fungal infections caused by one of the following:

- Aspergillus
- Candida

AND

2 - One of the following:

2.1 For Noxafil (posaconazole) oral tablet, both of the following:

- Patient is 2 years of age and older
- Patient weighs greater than 40kg

OR

2.2 For Noxafil oral suspension, patient is 13 years of age and older

OR

2.3 For Noxafil PowderMix, both of the following:

- Patient is 2 years of age and older

- Patient weighs 40 kg or less

AND

3 - Submission of medical records (e.g., chart notes) documenting one of the following:

3.1 Patient is at high risk of infections due to severe immunosuppression from one of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy

OR

3.2 Patient has a prior fungal infection requiring secondary prophylaxis [15, G]

Product Name:Brand Noxafil oral tablet, generic posaconazole oral tablet	
Diagnosis	Treatment of systemic fungal infections
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Brand
POSACONAZOLE DR	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic
POSACONAZOLE	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic

Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - Patient is 13 years of age and older

Product Name:Brand Noxafil oral tablet, generic posaconazole oral tablet	
Diagnosis	Treatment of systemic fungal infections
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Brand
POSACONAZOLE DR	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic
POSACONAZOLE	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic

Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - Patient is 13 years of age and older

Product Name:Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Invasive Aspergillosis
Approval Length	6 Months [16, B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VORICONAZOLE	VORICONAZOLE TAB 50 MG	11407080000320	Generic
VFEND	VORICONAZOLE TAB 50 MG	11407080000320	Brand
VORICONAZOLE	VORICONAZOLE TAB 200 MG	11407080000340	Generic
VFEND	VORICONAZOLE TAB 200 MG	11407080000340	Brand
VORICONAZOLE	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Generic
VFEND	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Brand

Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - Patient is 2 years of age and older

Product Name:Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Serious Fungal Infections
Approval Length	6 Months [16, B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VORICONAZOLE	VORICONAZOLE TAB 50 MG	11407080000320	Generic
VFEND	VORICONAZOLE TAB 50 MG	11407080000320	Brand
VORICONAZOLE	VORICONAZOLE TAB 200 MG	11407080000340	Generic
VFEND	VORICONAZOLE TAB 200 MG	11407080000340	Brand
VORICONAZOLE	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Generic
VFEND	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Brand

Approval Criteria

1 - Diagnosis of serious fungal infections (e.g., Scedosporium apiospermum, Fusarium species including Fusarium solani)

AND

2 - Patient is 2 years of age and older

AND

3 - Patient is intolerant of, or refractory to, other therapy (e.g., amphotericin B)

Product Name:Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Candidemia in non-neutropenic patients and other deep tissue Candida infections
Approval Length	1 Month [H, 16]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VORICONAZOLE	VORICONAZOLE TAB 50 MG	11407080000320	Generic
VFEND	VORICONAZOLE TAB 50 MG	11407080000320	Brand
VORICONAZOLE	VORICONAZOLE TAB 200 MG	11407080000340	Generic
VFEND	VORICONAZOLE TAB 200 MG	11407080000340	Brand
VORICONAZOLE	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Generic
VFEND	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Candidemia
- Deep tissue Candida infection (e.g., disseminated in skin, infection in abdomen, kidney, bladder wall, and wounds)

AND

2 - Patient is non-neutropenic

AND

3 - Patient is 2 years of age and older

AND

4 - One of the following:

- Trial and failure, contraindication or intolerance to fluconazole [I]
- Susceptibility results demonstrate resistance to fluconazole [K]

Product Name:Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Esophageal Candidiasis
Approval Length	1 Month [H, 16]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VORICONAZOLE	VORICONAZOLE TAB 50 MG	11407080000320	Generic
VFEND	VORICONAZOLE TAB 50 MG	11407080000320	Brand
VORICONAZOLE	VORICONAZOLE TAB 200 MG	11407080000340	Generic
VFEND	VORICONAZOLE TAB 200 MG	11407080000340	Brand
VORICONAZOLE	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Generic
VFEND	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Brand

Approval Criteria

1 - Diagnosis of esophageal candidiasis

AND

2 - Patient is 2 years of age and older

AND

3 - One of the following:

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

3 . Endnotes

A. Fingernail infections are usually reevaluated 18 weeks or longer after completion of therapy. Toenail infections are usually reevaluated 6-9 months after completion of therapy. [5] Indeed, considering that toenails can take 12 to 18 months to grow out, many clinicians consider that 1 year is too short to assess clinical effectiveness. [6] Reports of long-term follow-up of treated patients have recently been presented, suggesting that positive mycology at 12 and 24 weeks after commencement of therapy are poor prognostic signs and may indicate a need for retreatment or for a change of drug. [8]
B. The optimal duration of therapy for aspergillosis has not been defined. Most clinicians treat infections (pulmonary) until resolution or stabilization of clinical and radiographic manifestations. The IDSA recommends a minimal treatment period of 6 – 12 weeks in immunocompetent patients for invasive conditions. [11]
C. According to the IDSA guidelines for aspergillosis, duration of therapy for most conditions for aspergillosis has not been optimally defined. Most experts attempt to treat pulmonary infection until resolution or stabilization of all clinical and radiographic manifestations. Other factors include site of infection (e.g., osteomyelitis), level of immunosuppression, and extent of disease. Reversal of immunosuppression, if feasible, is important for a favorable outcome for invasive aspergillosis." [11]
D. According to the IDSA guidelines for the treatment of aspergillosis, both Amphotericin B and itraconazole are listed as second line treatment options for the treatment of invasive disease. [11]
E. For fluconazole-refractory OPC, either itraconazole or posaconazole for up to 28 days is recommended. For fluconazole-refractory esophageal candidiasis, itraconazole or voriconazole for 14 to 21 days is recommended. [3, 5]
F. Patients may be expected to relapse shortly after discontinuing therapy with Sporanox oral solution. Limited data on the safety of long-term use (> 6 months) of Sporanox Oral Solution are available at this time. [2]
G. NCCN recommends secondary prophylaxis with an appropriate antifungal agent in patients with prior chronic disseminated candidiasis or with invasive filamentous fungal infection during subsequent cycles of chemotherapy or HSCT. In patients with invasive aspergillosis before HSCT, antifungal therapy for more than a month and resolution of radiologic abnormalities correlate with a lower likelihood of post-transplant recurrence of infection. Secondary prophylaxis with a mold-active agent is advised for the entire period of immunosuppression. Secondary prophylaxis is generally administered for the duration of immunosuppression. Per recommendation from an infectious disease specialist, posaconazole is used for secondary prophylaxis of prior fungal infections. [15]
H. Voriconazole prescribing information states that for candidemia in non-neutropenic patients and other deep tissue Candida infections, patients should be treated for at least

14 days following resolution of symptoms or following last positive culture, whichever is long. For esophageal candidiasis, patients should be treated for a minimum of 14 days and for at least 7 days following resolution of symptoms. [16]

I. According to the 2016 IDSA guideline for candidemia in nonneutropenic patients, fluconazole, intravenous or oral, is an acceptable alternative to an echinocandin (e.g., caspofungin, micafungin, anidulafungin) in patients who are not critically ill and who are considered unlikely to have fluconazole-resistant Candida species. Voriconazole is effective for candidemia, however, offers little advantage over fluconazole as the initial therapy. [5]
J. According to the 2016 IDSA guideline for the treatment of esophageal candidiasis, oral fluconazole 200-400 mg for 14 to 21 days is strongly recommended (high-quality evidence). Intravenous fluconazole may be used in patients who cannot tolerate oral therapy. For fluconazole-refractory disease, voriconazole either intravenous or oral is recommended. [5]
K. Of the Candida species, C. krusei and C. glabrata are the two species with higher likelihood of fluconazole-resistance for serious candida infections due to widespread azole treatment. In these cases, voriconazole may be used as oral therapy in patients with infections due to C. krusei or fluconazole-resistant, voriconazole-susceptible C. glabrata infections. [5]

4 . References

1. Sporanox Capsules Prescribing Information. Janssen Pharmaceuticals, Inc.; Titusville, NJ. November 2023.
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10. Chapman SW, Dismukes WE, Proia LA, et al. Clinical practice guidelines for the management of blastomycosis: 2008 update by the Infectious Diseases Society of America. Clin Infect Dis. 2008;46:1801-1812.

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13. Tolsura Prescribing Information. Mayne Pharma; Greenville, NC. July 2023.
14. Noxafil Prescribing Information. Merck Sharp & Dohme Corp.; Whitehouse Station, NJ. October 2023.
15. Per Clinical Consultation with an Infectious Disease Specialist. January 24, 2014.
16. Voriconazole Tablet Prescribing Information. Ajanta Pharma Limited.; Bridgewater, NJ. November 2022.
17. Cresemba Prescribing Information. Astellas Pharma US., Inc. Northbrook, IL. December 2023.
18. Vfend Prescribing Information.Roerig. New York, NY. November 2022.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228363
Guideline Name	Bacterial Vaginosis Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nuvessa
Bacterial Vaginosis Indicated for the treatment of bacterial vaginosis in females 12 years of age and older.
Drug Name: Cleocin suppository
Bacterial Vaginosis Indicated for 3-day treatment of bacterial vaginosis in non-pregnant women. There are no adequate and well-controlled studies of CLEOCIN Vaginal Ovules in pregnant women.
Drug Name: Brand Cleocin vaginal cream
Bacterial Vaginosis Indicated in the treatment of bacterial vaginosis (formerly referred to as Haemophilus vaginitis, Gardnerella vaginitis, nonspecific vaginitis, Corynebacterium vaginitis, or anaerobic vaginosis). CLEOCIN Vaginal Cream 2%, can be used to treat non-pregnant women and pregnant women during the second and third trimester.
Drug Name: Solosec (secnidazole)

Bacterial Vaginosis Indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older.

Trichomonasis Indicated for the treatment of trichomoniasis in patients 12 years of age and older.

Drug Name: Brand Vandazole (metronidazole gel)

Bacterial Vaginosis Indicated in the treatment of bacterial vaginosis (formerly referred to as Haemophilus vaginitis, Gardnerella vaginitis, nonspecific vaginitis, Corynebacterium vaginitis, or anaerobic vaginosis) in post-menarchal females.

2 . Criteria

Product Name:Nuvessa, Cleocin suppository, Brand Cleocin vaginal cream, Brand Vandazole	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
NUVESSA	METRONIDAZOLE VAGINAL GEL 1.3%	55100035004030	Brand
CLEOCIN	CLINDAMYCIN PHOSPHATE VAGINAL CREAM 2%	55100018103720	Brand
CLEOCIN	CLINDAMYCIN PHOSPHATE VAGINAL SUPPOS 100 MG	55100018105220	Brand
VANDAZOLE	METRONIDAZOLE VAGINAL GEL 0.75%	55100035004020	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Trial and failure of a minimum 5 day supply within the past 180 days, contraindication, or intolerance to generic metronidazole 0.75% vaginal gel

OR

2.2 Trial and failure of a minimum 3 day supply within the past 180 days, contraindication, or intolerance to clindamycin 2% vaginal cream

Product Name:Solosec	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
SOLOSEC	SECNIDAZOLE GRANULES PACKET 2 GM	14000080003020	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of bacterial vaginosis

AND

1.1.2 One of the following:

1.1.2.1 Trial and failure of a minimum 5 day supply within the past 180 days, contraindication, or intolerance to:

- generic metronidazole 0.75% vaginal gel

OR

1.1.2.2 Trial and failure of a minimum 3 day supply within the past 180 days, contraindication, or intolerance to:

- generic clindamycin 2% vaginal cream

OR

1.2 Both of the following:

1.2.1 Diagnosis of trichomoniasis

AND

1.2.2 Trial and failure within the past 180 days, contraindication, or intolerance to ONE of the following generics: [6]

- metronidazole tablet
- tinidazole tablet

3 . References

1. Nuvessa [package insert]. Florham Park, NJ.: Exeltis USA, Inc.; April 2022.
2. Cleocin vaginal ovules [package insert]. New York, NY.: Pfizer, Inc.; February 2024.
3. Cleocin vaginal cream [package insert]. New York, NY.: Pfizer, Inc.; November 2022.
4. Solosec Prescribing Information. Lupin Pharmaceuticals, Inc. Baltimore, MD. January 2022.
5. Vandazole Prescribing Information. Upsher-smith Laboratories, LLC. Maple Grove, MN. February 2021.
6. Trichomoniasis - STI Treatment Guidelines. (2021, July 20). Www.cdc.gov. https://www.cdc.gov/std/treatment-guidelines/trichomoniasis.htm

Prior Authorization Guideline

Guideline ID	GL-228365
Guideline Name	Balversa (erdafitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Balversa (erdafitinib)
Urothelial Carcinoma Indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) with susceptible FGFR3 genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy. Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA. Limitations of Use: BALVERSA is not recommended for the treatment of patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.

2 . Criteria

Product Name:Balversa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BALVERSA	ERDAFITINIB TAB 3 MG	21532225000320	Brand
BALVERSA	ERDAFITINIB TAB 4 MG	21532225000325	Brand
BALVERSA	ERDAFITINIB TAB 5 MG	21532225000330	Brand

Approval Criteria

1 - Diagnosis of urothelial carcinoma

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Presence of susceptible fibroblast growth factor receptor (FGFR) 3 genetic alterations as detected by a U.S. Food and Drug Administration (FDA)-approved test (therascreen FGFR RGQ RT-PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Disease has progressed on or after at least one line of prior systemic therapy (e.g., chemotherapy)

AND

5 - One of the following:

5.1 Patient had been treated with prior PD-1 inhibitor therapy (e.g., Opdivo [nivolumab], Keytruda [pembrolizumab]) or PD-L1 inhibitor therapy (e.g., Bavencio [avelumab])

OR

5.2 Patient is not a candidate for PD-1 or PD-L1 inhibitor therapy

Product Name:Balversa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BALVERSA	ERDAFITINIB TAB 3 MG	21532225000320	Brand
BALVERSA	ERDAFITINIB TAB 4 MG	21532225000325	Brand
BALVERSA	ERDAFITINIB TAB 5 MG	21532225000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Balversa Prescribing Information. Janssen Products, LP. Horsham, PA. January 2024.

Prior Authorization Guideline

Guideline ID	GL-228802
Guideline Name	Banzel (rufinamide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Banzel (rufinamide) tablets and oral suspension
Lennox-Gastaut Syndrome (LGS) Indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in pediatric patients 1 year of age and older and in adults.

2 . Criteria

Product Name:Brand Banzel	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BANZEL	RUFINAMIDE TAB 200 MG	72600065000320	Brand
BANZEL	RUFINAMIDE TAB 400 MG	72600065000330	Brand
BANZEL	RUFINAMIDE SUSP 40 MG/ML	72600065001820	Brand

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gaustaut Syndrome (LGS)

AND

2 - Used as adjunctive therapy

AND

3 - Patient is 1 year of age or older

AND

4 - One of the following:

- Trial of and inadequate response to, contraindication, or intolerance to ONE generic formulary anticonvulsant (e.g., topiramate, lamotrigine, valproate)
- For continuation of prior therapy if the patient is established on Brand Banzel

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:generic rufinamide	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RUFINAMIDE	RUFINAMIDE SUSP 40 MG/ML	72600065001820	Generic
RUFINAMIDE	RUFINAMIDE TAB 200 MG	72600065000320	Generic
RUFINAMIDE	RUFINAMIDE TAB 400 MG	72600065000330	Generic

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gaustaut Syndrome (LGS)

AND

2 - Used as adjunctive therapy

AND

3 - Patient is 1 year of age or older

AND

4 - One of the following:

- Trial of and inadequate response to, contraindication, or intolerance to ONE generic formulary anticonvulsant (e.g., topiramate, lamotrigine, valproate) other than generic rufinamide
- For continuation of prior therapy if the patient is established on generic rufinamide

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Brand Banzel, generic rufinamide	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BANZEL	RUFINAMIDE TAB 200 MG	72600065000320	Brand
BANZEL	RUFINAMIDE TAB 400 MG	72600065000330	Brand
BANZEL	RUFINAMIDE SUSP 40 MG/ML	72600065001820	Brand
RUFINAMIDE	RUFINAMIDE SUSP 40 MG/ML	72600065001820	Generic
RUFINAMIDE	RUFINAMIDE TAB 200 MG	72600065000320	Generic
RUFINAMIDE	RUFINAMIDE TAB 400 MG	72600065000330	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Banzel Prescribing Information. Eisai Inc. Woodcliff, NJ. April 2020.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228367
Guideline Name	Bendamustine Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Belrapzo
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Bendamustine
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Drug Name: Bendeka
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Treanda
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Vivimusta
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

2 . Criteria

Product Name:Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Chronic lymphocytic leukemia (CLL)
Approval Length	6 Month(s) [A, C]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENDEKA	BENDAMUSTINE HCL IV SOLN 100 MG/4ML (25 MG/ML)	21100009102005	Brand
BELRAPZO	BENDAMUSTINE HCL IV SOLN 100 MG/4ML (25 MG/ML)	21100009102005	Brand

BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HCL IV SOLN 100 MG/4ML (25 MG/ML)	21100009102005	Brand
TREANDA	BENDAMUSTINE HCL FOR IV SOLN 25 MG	21100009102110	Brand
TREANDA	BENDAMUSTINE HCL FOR IV SOLN 100 MG	21100009102120	Brand
VIVIMUSTA	BENDAMUSTINE HCL IV SOLN 100 MG/4ML (25 MG/ML)	21100009102005	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to generic bendamustine

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Notes	If patient meets criteria above, please approve at NDC level.

Product Name:Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Non-Hodgkin lymphoma (NHL)
Approval Length	6 Month(s) [B, D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENDEKA	BENDAMUSTINE HCL IV SOLN 100 MG/4ML (25 MG/ML)	21100009102005	Brand
BELRAPZO	BENDAMUSTINE HCL IV SOLN 100 MG/4ML (25 MG/ML	21100009102005	Brand
BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HCL IV SOLN 100 MG/4ML (25 MG/ML)	21100009102005	Brand
TREANDA	BENDAMUSTINE HCL FOR IV SOLN 25 MG	21100009102110	Brand

TREANDA	BENDAMUSTINE HCL FOR IV SOLN 100 MG	21100009102120	Brand
VIVIMUSTA	BENDAMUSTINE HCL IV SOLN 100 MG/4ML (25 MG/ML)	21100009102005	Brand

Approval Criteria

1 - Diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL)

AND

2 - Disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to generic bendamustine

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Notes	If patient meets criteria above, please approve at NDC level.

Product Name:Generic bendamustine	
Diagnosis	Chronic lymphocytic leukemia (CLL)
Approval Length	6 Month(s) [C]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HCL FOR IV SOLN 25 MG	21100009102110	Generic
BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HCL FOR IV SOLN 100 MG	21100009102120	Generic

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)

Notes	If patient meets criteria above, please approve at NDC level.

Product Name:Generic bendamustine	
Diagnosis	Non-Hodgkin lymphoma (NHL)
Approval Length	6 Month(s) [D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HCL FOR IV SOLN 25 MG	21100009102110	Generic
BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HCL FOR IV SOLN 100 MG	21100009102120	Generic

Approval Criteria

1 - Diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL)

AND

2 - Disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen

Notes	If patient meets criteria above, please approve at NDC level.

3 . Endnotes

A. For Bendeka: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 10 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. [3]
B. For Bendeka: The recommended dose for non-Hodgkin lymphoma (NHL) is 120 mg/m2 administered intravenously over 10 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles. [3]

C. For Belrapzo, Bendamustine, Treanda: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 30 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. [1, 2, 4]
D. For Belrapzo, Bendamustine, Treanda: The recommended dose for non-Hodgkin lymphoma (NHL) is 120 mg/m2 administered intravenously over 60 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles. [1, 2, 4]
E. For Vivimusta: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 20 minutes on Days 1 and 2 of a 28-day cycle for up to 6 cycles. [5]
F. For Vivimusta: The recommended dose for non-Hodgkin lymphoma (NHL) is 20 mg/m2 administered intravenously over 20 minutes on Days 1 and 2 of a 21-day cycle for up to 8 cycles. [5]

4 . References

1. Belrapzo prescribing information. Eagle Pharmaceuticals, Inc. Woodcliff Lake, NJ. June 2022.
2. Bendamustine prescribing information. Eagle Pharmaceuticals, Inc. Woodcliff Lake, NJ. May 2019.
3. Bendeka prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA. October 2021.
4. Treanda prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA. June 2021.
5. Vivimusta prescribing information. Slayback Pharma LLC. Princeton, NJ. December 2022.

Benlysta (belimumab)

Prior Authorization Guideline

Guideline ID	GL-228804
Guideline Name	Benlysta (belimumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Benlysta (belimumab IV), Benlysta (belimumab SC)
Systemic Lupus Erythematosus (SLE) Indicated for the treatment of patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in these situations. **Lupus Nephritis** Indicated for the treatment of patients aged 5 years and older with active lupus nephritis who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in these situations.

2 . Criteria

Product Name:Benlysta SC prefilled syringe	
Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/ML	9942201500E520	Brand

Approval Criteria

1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

2 - Autoantibody positive (i.e., anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL) [2, 3]

AND

3 - Patient is 18 years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [5]

AND

5 - Currently receiving at least one standard of care treatment for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [2, 3]

AND

6 - Prescribed by or in consultation with a rheumatologist

Product Name:Benlysta IV or Benlysta SC autoinjector	
Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENLYSTA	BELIMUMAB FOR IV SOLN 120 MG	99422015002120	Brand
BENLYSTA	BELIMUMAB FOR IV SOLN 400 MG	99422015002140	Brand
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/ML	9942201500D520	Brand

Approval Criteria

1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

2 - Autoantibody positive (i.e., anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL) [2, 3]

AND

3 - Patient is 5 years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to two standard of care treatments for

active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [5]

AND

5 - Currently receiving at least one standard of care treatment for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [2, 3]

AND

6 - Prescribed by or in consultation with a rheumatologist

Product Name:Benlysta IV or Benlysta SC	
Diagnosis	Lupus nephritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENLYSTA	BELIMUMAB FOR IV SOLN 120 MG	99422015002120	Brand
BENLYSTA	BELIMUMAB FOR IV SOLN 400 MG	99422015002140	Brand
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/ML	9942201500D520	Brand
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/ML	9942201500E520	Brand

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - One of the following:

- For Benlysta IV, patient is 5 years of age or older
- For Benlysta SC, patient is 18 years of age or older

AND

3 - Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide) [1, 4]

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Rheumatologist

Product Name:Benlysta IV or Benlysta SC	
Diagnosis	All indications listed above
Approval Length	6 months [2, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENLYSTA	BELIMUMAB FOR IV SOLN 120 MG	99422015002120	Brand
BENLYSTA	BELIMUMAB FOR IV SOLN 400 MG	99422015002140	Brand
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/ML	9942201500D520	Brand
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/ML	9942201500E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decrease or stabilization of symptoms, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications)

3 . Endnotes

A. SLE is a disease that fluctuates. The undulating course of typical lupus patients requires frequent reassessment. A 6-month authorization period is reasonable. [2]

4 . References

1. Benlysta Prescribing Information. GlaxoSmithKline LLC. Philadelphia, PA. June 2024.
2. Per clinical consult with rheumatologist, October 4, 2017.
3. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus. Arthritis Rheum. 1999 Sep;42(9):1785-96.
4. American College of Rheumatology Guidelines for Screening, Case Definition, Treatment and Management of Lupus Nephritis. Arthritis Care Res (Hoboken). 2012 Jun; 64(6): 797-808.
5. Fanouriakis A, Kostopoulou M, Alunno A, et al. Ann Rheum Dis 2019;78:736–745.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228369
Guideline Name	Besremi (ropeginterferon alfa-2b-njft) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Besremi (ropeginterferon alfa-2b-njft)
Polycythemia Vera Indicated for the treatment of adults with polycythemia vera.

2 . Criteria

Product Name:Besremi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

BESREMI	ROPEGINTERFERON ALFA-2B-NJFT SOLN PREFILLED SYR 500 MCG/ML	2170007750E520	Brand

Approval Criteria

1 - Diagnosis of polycythemia vera as confirmed by all of the following [A]:

1.1 One of the following:

- Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women
- Hematocrit greater than 49% for men or hematocrit greater than 48% for women
- Increased red cell mass

AND

1.2 Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes

AND

1.3 One of the following:

- Presence of JAK2 or JAK2 exon 12 mutation
- Subnormal serum erythropoietin level

AND

2 - One of the following:

2.1 For high-risk polycythemia vera only (patient greater than or equal to 60 years old and/or prior thrombosis history), trial and inadequate response, contraindication or intolerance to hydroxyurea

OR

2.2 For continuation of prior therapy

Product Name:Besremi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BESREMI	ROPEGINTERFERON ALFA-2B-NJFT SOLN PREFILLED SYR 500 MCG/ML	2170007750E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in hematological response, resolution of splenomegaly, absence of thromboembolic events) [2]

Product Name:Besremi	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
BESREMI	ROPEGINTERFERON ALFA-2B-NJFT SOLN PREFILLED SYR 500 MCG/ML	2170007750E520	Brand

Approval Criteria

1 - Diagnosis of polycythemia vera as confirmed by all of the following [A]:

1.1 One of the following:

- Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women
- Hematocrit greater than 49% for men or hematocrit greater than 48% for women
- Increased red cell mass

AND

1.2 Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes

AND

1.3 One of the following:

- Presence of JAK2 or JAK2 exon 12 mutation
- Subnormal serum erythropoietin level

AND

2 - One of the following:

2.1 For high-risk polycythemia vera only (patient greater than or equal to 60 years old and/or prior thrombosis history), submission of medical records (e.g., chart notes) confirming trial and inadequate response, contraindication or intolerance to hydroxyurea

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . Endnotes

A. According to the World Health Organization (WHO), diagnosis of polycythemia vera requires meeting either all three major criteria or the first two major criteria and one minor criterion. The three major criteria are as follows: 1) Hemoglobin > 16.5 g/dL for men or hemoglobin > 16.0 g/dL for women, or Hematocrit > 49% for men or Hematocrit > 48% for women, or increased red cell mass; 2) Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes (differences in size); 3) Presence of JAK2 or JAK2 exon 12 mutation. The minor criterion is subnormal serum erythropoietin level. [3]

4 . References

1. BESREMi (ropeginterferon alfa-2b-njft) [Prescribing Information]. Taipei, Taiwan. PharmaEssentia Corporation. November 2021.
2. Vannucchi A, Barbui T, Cervantes F et al. Philadelphia chromosome-negative chronic myeloproliferative neoplasms: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology. 2015;26:v85-v99.
3. Barbui T, Thiele J, Gisslinger H et al. The 2016 WHO classification and diagnostic criteria for myeloproliferative neoplasms: document summary and in-depth discussion. Blood Cancer J. 2018;8(2)
4. Abu-Zeinah, G., Krichevsky, S., Cruz, T. et al. Interferon-alpha for treating polycythemia vera yields improved myelofibrosis-free and overall survival. Leukemia 35, 2592–2601 (2021).
5. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Myeloproliferative Neoplasms v2.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed August 19, 2024.

Prior Authorization Guideline

Guideline ID	GL-228801
Guideline Name	Bevacizumab - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Avastin (bevacizumab)
Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab product-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer. **First-line Non-Squamous Non–Small Cell Lung Cancer (NSCLC)** Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel. **Recurrent Glioblastoma** Indicated for the treatment of recurrent glioblastoma in adults. **Metastatic Renal Cell Carcinoma (mRCC)** Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa. **Persistent, Recurrent, or Metastatic Cervical Cancer** Indicated for the treatment of

persistent, recurrent, or metastatic cervical cancer when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Hepatocellular Carcinoma Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

Drug Name: Mvasi (bevacizumab-awwb), Zirabev (bevacizumab-bvzr), Alymsys (bevacizumab-maly), Vegzelma (bevacizumab-adcd)

Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab product-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer.

First-line Non-Squamous Non–Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel.

Recurrent Glioblastoma Indicated for the treatment of recurrent glioblastoma in adults.

Metastatic Renal Cell Carcinoma (mRCC) Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Cervical Cancer Indicated for the treatment of persistent, recurrent, or metastatic cervical cancer when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent,

for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Off Label Uses: **Hepatocellular Carcinoma** Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. [4, A]

2 . Criteria

Product Name:Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AVASTIN	BEVACIZUMAB IV SOLN 100 MG/4ML (FOR INFUSION)	21335020002025	Brand
AVASTIN	BEVACIZUMAB IV SOLN 400 MG/16ML (FOR INFUSION)	21335020002030	Brand
MVASI	BEVACIZUMAB-AWWB IV SOLN 100 MG/4ML (FOR INFUSION)	21335020202025	Brand
MVASI	BEVACIZUMAB-AWWB IV SOLN 400 MG/16ML (FOR INFUSION)	21335020202030	Brand
ZIRABEV	BEVACIZUMAB-BVZR IV SOLN 100 MG/4ML (FOR INFUSION)	21335020302025	Brand
ZIRABEV	BEVACIZUMAB-BVZR IV SOLN 400 MG/16ML (FOR INFUSION)	21335020302030	Brand
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 100 MG/4ML (FOR INFUSION)	21335020502025	Brand
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 400 MG/16ML (FOR INFUSION)	21335020502030	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 100 MG/4ML (FOR INFUSION)	21335020102025	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 400 MG/16ML (FOR INFUSION)	21335020102030	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Requested medication is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

AND

2 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

2.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AVASTIN	BEVACIZUMAB IV SOLN 100 MG/4ML (FOR INFUSION)	21335020002025	Brand
AVASTIN	BEVACIZUMAB IV SOLN 400 MG/16ML (FOR INFUSION)	21335020002030	Brand
MVASI	BEVACIZUMAB-AWWB IV SOLN 100 MG/4ML (FOR INFUSION)	21335020202025	Brand
MVASI	BEVACIZUMAB-AWWB IV SOLN 400 MG/16ML (FOR INFUSION)	21335020202030	Brand
ZIRABEV	BEVACIZUMAB-BVZR IV SOLN 100 MG/4ML (FOR INFUSION)	21335020302025	Brand
ZIRABEV	BEVACIZUMAB-BVZR IV SOLN 400 MG/16ML (FOR INFUSION)	21335020302030	Brand
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 100 MG/4ML (FOR INFUSION)	21335020502025	Brand
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 400 MG/16ML (FOR INFUSION)	21335020502030	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 100 MG/4ML (FOR INFUSION)	21335020102025	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 400 MG/16ML (FOR INFUSION)	21335020102030	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

2.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Alymsys, Vegzelma	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 100 MG/4ML (FOR INFUSION)	21335020502025	Brand
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 400 MG/16ML (FOR INFUSION)	21335020502030	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 100 MG/4ML (FOR INFUSION)	21335020102025	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 400 MG/16ML (FOR INFUSION)	21335020102030	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Requested medication is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

3 . Endnotes

A. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [4]

4 . References

1. Avastin Prescribing Information. Genentech Inc. South San Francisco, CA. September 2022.
2. Mvasi Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2023.
3. Zirabev Prescribing Information. Pfizer Inc. New York, NY. February 2023.
4. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed December 4, 2023.

5. Alymsys Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. April 2022.
6. Vegzelma Prescribing Information. Celltrion USA, Inc. Jersey City, NJ. February 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229086
Guideline Name	Bimzelx (bimekizumab-bkzx)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Bimzelx (bimekizumab-bkzx)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)** Indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis.

2 . Criteria

Product Name:Bimzelx	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN AUTO-INJECTOR 160 MG/ML	9025051800D520	Brand
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN PREFILLED SYR 160 MG/ML	9025051800E520	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- At least 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product*
- One formulary ustekinumab product*
- Cosentyx (secukinumab)
- Skyrizi (risankizumab)
- Tremfya (guselkumab)
- Otezla (apremilast)
- Sotyktu (deucravacitinib)

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name:Bimzelx	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN AUTO-INJECTOR 160 MG/ML	9025051800D520	Brand
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN PREFILLED SYR 160 MG/ML	9025051800E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction in the body surface area (BSA) involvement from baseline

- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Bimzelx	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN AUTO-INJECTOR 160 MG/ML	9025051800D520	Brand
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN PREFILLED SYR 160 MG/ML	9025051800E520	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product*
- Simponi (golimumab)
- One formulary ustekinumab product*
- Cosentyx (secukinumab)
- Skyrizi (risankizumab)
- Tremfya (guselkumab)
- Rinvoq/LQ (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

Notes	* For review process only: Refer to the table in the Background section for carrier-specific formulary products

Product Name:Bimzelx	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN AUTO-INJECTOR 160 MG/ML	9025051800D520	Brand
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN PREFILLED SYR 160 MG/ML	9025051800E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name:Bimzelx	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN AUTO-INJECTOR 160 MG/ML	9025051800D520	Brand
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN PREFILLED SYR 160 MG/ML	9025051800E520	Brand

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA)

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 5]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- Cosentyx (secukinumab)
- Rinvoq (upadacitinib)

OR

5.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Bimzelx	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN AUTO-INJECTOR 160 MG/ML	9025051800D520	Brand
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN PREFILLED SYR 160 MG/ML	9025051800E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Function
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name:Bimzelx	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN AUTO-INJECTOR 160 MG/ML	9025051800D520	Brand
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN PREFILLED SYR 160 MG/ML	9025051800E520	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis (AS)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product*
- Simponi (golimumab)
- Cosentyx (secukinumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

Notes	* For review process only: Refer to the table in the Background section for carrier-specific formulary products

Product Name:Bimzelx	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN AUTO-INJECTOR 160 MG/ML	9025051800D520	Brand
BIMZELX	BIMEKIZUMAB-BKZX SUBCUTANEOUS SOLN PREFILLED SYR 160 MG/ML	9025051800E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Function
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products **Adalimumab-adaz** **Hyrimoz** **Hadlima** **Adalimumab-fkjp**

4 . References

1. Bimzelx Prescribing Information. UCB, Inc. Smyrna, GA. October 2024.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

5 . Revision History

Date	Notes
12/20/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-228625
Guideline Name	Blood Glucose Monitor & Test Strips - QL
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

Note:

This guideline does not apply to continuous glucose monitors.

1 . Indications

Drug Name: Blood glucose monitoring systems
Quantitative measurements of glucose Intended to be used for quantitative measurements of glucose in fresh capillary and/or venous whole blood. Various devices are designed for testing by persons with diabetes or by health care professionals in the home or health care facilities.

2 . Criteria

Product Name:Preferred or non-preferred test strip products	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
GLUCOSE TEST STRIPS	glucose test strip	94100030	
BLOOD GLUCOSE TEST STRIPS	GLUCOSE BLOOD TEST STRIP	94100030006100	Brand

Approval Criteria

1 - Physician confirmation that the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions) [A]

3 . Endnotes

A. The evidence regarding the utility and optimal frequency of blood glucose monitoring (BGM) is not well defined for patients who do not use intensive insulin regimens, such as those with type 2 diabetes using oral agents and/or basal insulin [1]. However for most patients using intensive insulin regimens (multiple-dose insulin or insulin pump therapy) BGM should be performed prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to and while performing critical tasks such as driving [1].

4 . References

1. American Diabetes Association (ADA). Diabetes Technology: Standards of Medical Care in Diabetes - 2023. Diabetes Care. 2023;46(suppl 1):S111-S127.

5 . Revision History

Date	Notes
11/7/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-228372
Guideline Name	Bonjesta, Diclegis (doxylamine/pyridoxine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Bonjesta, Diclegis (doxylamine succinate and pyridoxine hydrochloride)
Nausea and vomiting of pregnancy Indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. Limitations of Use: Bonjesta and Diclegis have not been studied in women with hyperemesis gravidarum.

2 . Criteria

Product Name:Bonjesta, Brand Diclegis, Generic doxylamine/pyridoxine delayed-release			
Approval Length	9 Months		
Guideline Type	Prior Authorization		
Product Name	Generic Name	GPI	Brand/Generic

DICLEGIS	DOXYLAMINE-PYRIDOXINE TAB DELAYED RELEASE 10-10 MG	50309902100620	Brand
BONJESTA	DOXYLAMINE-PYRIDOXINE TAB ER 20-20 MG	50309902100430	Brand
DOXYLAMINE SUCCINATE/PYRIDOXINE HYDROCHLORIDE	DOXYLAMINE-PYRIDOXINE TAB DELAYED RELEASE 10-10 MG	50309902100620	Generic

Approval Criteria

1 - Diagnosis of nausea and vomiting of pregnancy

AND

2 - Trial and failure or intolerance to generic doxylamine and generic pyridoxine (Vitamin B6) taken together [5, 7]

3 . Endnotes

A. Bonjesta and Diclegis (doxylamine succinate/pyridoxine hydrochloride) are contraindicated in women who are taking monoamine oxidase inhibitors (MAOIs), which prolong and intensify the anticholinergic (drying) effects of antihistamines. [1, 6]

4 . References

1. Diclegis prescribing information. Duchesnay USA, Inc. Bryn Mawr, PA. June 2023.
2. ACOG Practice Bulletin. Nausea and vomiting of pregnancy. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2018; 131(1): 190-193. (Practice Bulletin No. 189)
3. Arsenault MY, Lane CA. The Management of Nausea and Vomiting in Pregnancy. J Obstet Gynaecol Can 2002; 24(10):817-23.
4. Ebrahimi N, Maltepe C, Einarson A. Optimal management of nausea and vomiting of pregnancy. Int J Womens Health. 2010; 2: 241–248.
5. Matthews A, Haas DM, O'Mathúna DP, et al. Interventions for nausea and vomiting in early pregnancy. Cochrane Database Syst Rev. 2015 Sep 8; 9:CD007575.
6. Bonjesta prescribing information. Duchesnay USA, Inc. Bryn Mawr, PA. October 2022.
7. Campbell K, Rowe H, Azzam H, Lane C. The Management of Nausea and Vomiting of Pregnancy. Journal of Obstetrics and Gynaecology Canada. 2016;38(12):1127-1137. doi:10.1016/j.jogc.2016.08.009

Prior Authorization Guideline

Guideline ID	GL-228373
Guideline Name	Bortezomib
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Velcade (bortezomib)
Multiple Myeloma Indicated for the treatment of patients with multiple myeloma. **Mantle Cell Lymphoma** Indicated for the treatment of patients with mantle cell lymphoma.
Drug Name: Bortezomib (bortezomib)
Multiple Myeloma Indicated for the treatment of patients with multiple myeloma. **Mantle Cell Lymphoma** Indicated for the treatment of adult patients with mantle cell lymphoma.

2 . Criteria

Product Name:Brand Velcade, Generic bortezomib, Bortezomib	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VELCADE	BORTEZOMIB FOR INJ 3.5 MG	21536015002120	Brand
BORTEZOMIB	BORTEZOMIB FOR IV INJ 3.5 MG	21536015002122	Brand
BORTEZOMIB	BORTEZOMIB FOR INJ 3.5 MG	21536015002120	Generic
BORTEZOMIB	BORTEZOMIB FOR INJ 2.5 MG	21536015002113	Generic
BORTEZOMIB	BORTEZOMIB FOR INJ 1 MG	21536015002110	Generic
BORTEZOMIB	BORTEZOMIB INJ 3.5 MG/1.4ML	21536015002030	Generic
BORTEZOMIB	BORTEZOMIB IV SOLN 3.5 MG/1.4ML	21536015002032	Generic

Approval Criteria

1 - Diagnosis of multiple myeloma [1, 2, 5]

AND

2 - Trial and failure, contraindication or intolerance to generic bortezomib (Applies to Brand Velcade Only)

Product Name:Brand Velcade, Generic bortezomib, Bortezomib	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VELCADE	BORTEZOMIB FOR INJ 3.5 MG	21536015002120	Brand

BORTEZOMIB	BORTEZOMIB FOR IV INJ 3.5 MG	21536015002122	Brand
BORTEZOMIB	BORTEZOMIB FOR INJ 3.5 MG	21536015002120	Generic
BORTEZOMIB	BORTEZOMIB FOR INJ 2.5 MG	21536015002113	Generic
BORTEZOMIB	BORTEZOMIB FOR INJ 1 MG	21536015002110	Generic
BORTEZOMIB	BORTEZOMIB INJ 3.5 MG/1.4ML	21536015002030	Generic
BORTEZOMIB	BORTEZOMIB IV SOLN 3.5 MG/1.4ML	21536015002032	Generic

Approval Criteria

1 - Diagnosis of mantle cell lymphoma [1, 3, 4, 5]

AND

2 - Trial and failure, contraindication or intolerance to generic bortezomib (Applies to Brand Velcade Only)

Product Name:Brand Velcade, Generic bortezomib, Bortezomib	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VELCADE	BORTEZOMIB FOR INJ 3.5 MG	21536015002120	Brand
BORTEZOMIB	BORTEZOMIB FOR IV INJ 3.5 MG	21536015002122	Brand
BORTEZOMIB	BORTEZOMIB FOR INJ 3.5 MG	21536015002120	Generic
BORTEZOMIB	BORTEZOMIB FOR INJ 2.5 MG	21536015002113	Generic
BORTEZOMIB	BORTEZOMIB FOR INJ 1 MG	21536015002110	Generic
BORTEZOMIB	BORTEZOMIB INJ 3.5 MG/1.4ML	21536015002030	Generic
BORTEZOMIB	BORTEZOMIB IV SOLN 3.5 MG/1.4ML	21536015002032	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Velcade Prescribing Information. Millennium Pharmaceuticals, Inc. Cambridge, MA. November 2021.
2. Richardson PG, Sonneveld P, Schuster MW, et al. Assessment of Proteasome Inhibition for Extending Remissions (APEX) Investigators. Bortezomib or high-dose dexamethasone for relapsed multiple myeloma. N Engl J Med. 2005 Jun 16;352(24):2487-98.
3. National Cancer Institute. Adult Non-Hodgkin Lymphoma Treatment (PDQ). Available at: http://www.cancer.gov/cancertopics/pdq/treatment/adult-non-hodgkins/healthprofessional. Accessed May 12, 2022.
4. Fisher RI, Bernstein SH, Kahl BS, et al. Multicenter phase II study of bortezomib in patients with relapsed or refractory mantle cell lymphoma. J Clin Oncol.2006;24(30):4867-74.
5. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org. Accessed May 12, 2022.
6. Bortezomib Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. December 2022.
7. Bortezomib Prescribing Information. Hospira, Inc.. Lake Forest, IL. December 2022.
8. Bortezomib Prescribing Information. Dr Reddy’s Laboratories, Inc. Princeton, NJ. December 2022.
9. Bortezomib Prescribing Information. Hikma Pharmaceuticals USA, Inc. Berkeley Heights, NJ. November 2021.
10. Bortezomib Prescribing Information. Fosun Pharma USA. Princeton, NJ. August 2022.

Prior Authorization Guideline

Guideline ID	GL-229096
Guideline Name	Bosulif (bosutinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/13/2012
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Bosulif (bosutinib)
Accelerated or Blast Phase Chronic Myelogenous/Myeloid Leukemia Indicated for the treatment of adult patients with accelerated or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy. **Chronic Phase Chronic Myelogenous Leukemia** Indicated for the treatment of adult and pediatric patients 1 year of age and older with chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), newly-diagnosed or resistant or intolerant to prior therapy.

2 . Criteria

Product Name:Bosulif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOSULIF	BOSUTINIB TAB 100 MG	21531812000320	Brand
BOSULIF	BOSUTINIB TAB 400 MG	21531812000327	Brand
BOSULIF	BOSUTINIB TAB 500 MG	21531812000340	Brand
BOSULIF	BOSUTINIB CAP 50 MG	21531812000120	Brand
BOSULIF	BOSUTINIB CAP 100 MG	21531812000130	Brand

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia (Ph+ CML) [1, 2]

AND

2 - One of the following:

2.1 Disease is in the accelerated or blast phase

OR

2.2 Both of the following:

2.2.1 Both of the following:

- Disease is in the chronic phase
- Patient is 1 year of age or older

AND

2.2.2 One of the following:

2.2.2.1 Trial and failure, contraindication, or intolerance to BOTH of the following:

- generic dasatinib
- generic imatinib

OR

2.2.2.2 Continuation of prior therapy

Product Name:Bosulif	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOSULIF	BOSUTINIB TAB 100 MG	21531812000320	Brand
BOSULIF	BOSUTINIB TAB 400 MG	21531812000327	Brand
BOSULIF	BOSUTINIB TAB 500 MG	21531812000340	Brand
BOSULIF	BOSUTINIB CAP 50 MG	21531812000120	Brand
BOSULIF	BOSUTINIB CAP 100 MG	21531812000130	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to BOTH of the following:

- generic dasatinib
- generic imatinib

OR **2.2** Continuation of prior therapy

3 . References

1. Bosulif Prescribing Information. Pfizer. New York, NY. September 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on March 18, 2020.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-233325
Guideline Name	Botox (onabotulinumtoxinA)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/18/2025
P&T Approval Date:	3/17/2000
P&T Revision Date:	12/18/2024

1 . Indications

Drug Name: Botox (onabotulinumtoxin A)
Adult Bladder Dysfunction 1) Overactive Bladder: Indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication. 2) Detrusor Overactivity associated with a Neurologic Condition: Indicated for the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication. 2) Detrusor Overactivity associated with a Neurologic Condition: Indicated for the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication. **Pediatric Detrusor Overactivity associated with a Neurologic Condition** Indicated for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication.

Chronic Migraine Indicated for the prophylaxis of headaches in adult patients with chronic migraine (greater than or equal to 15 days per month with headache lasting 4 hours a day or longer). Important Limitations: Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies.

Spasticity Indicated for the treatment of spasticity in patients 2 years of age and older. Limitations of use: Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.

Cervical Dystonia (Spasmodic Torticollis) Indicated for the treatment of cervical dystonia in adults to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

Primary Axillary Hyperhidrosis Indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. Limitations of use: The safety and effectiveness of Botox for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive Botox for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease. Safety and effectiveness of Botox have not been established for the treatment of axillary hyperhidrosis in pediatric patients under age 18.

Blepharospasm and strabismus Indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders (involving muscles of the face) in patients 12 years of age and above.

Off Label Uses: **Chronic Low Back Pain [2, 3]** Used in the treatment of chronic low back pain.

Other Uses [2, 3] Used in the treatment of achalasia, chronic anal fissures, dynamic muscle contracture in pediatric cerebral palsy patients, sialorrhea, hand tremor, and oromandibular dystonia.

Drug Name: Botox Cosmetic (onabotulinumtoxin A)

Cosmetic Uses [Non-approvable Use] Indicated in adult patients for the temporary improvement in the appearance of: 1) Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity 2) Moderate to severe lateral canthal lines associated with orbicularis oculi activity 3) Moderate to severe forehead lines associated with frontalis muscle activity 4) Moderate to severe platysma bands associated with platysma muscle activity **Please Note: The request for Botox (onabotulinumtoxin A) injections to treat the appearance of facial lines is not authorized given that this use is for cosmetic purposes only.

2 . Criteria

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Adult Bladder Dysfunction OR Neurogenic Detrusor Overactivity (NDO)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - One of the following conditions: [1, 3, E, F]

- Urinary incontinence that is associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis)
- Overactive bladder with symptoms (e.g., urge urinary incontinence, urgency, and frequency)
- Neurogenic detrusor overactivity (NDO)

AND

2 - Trial and failure, contraindication, or intolerance to at least one oral anticholinergic (antispasmodic or antimuscarinic) agent [e.g., Bentyl (dicyclomine), Donnatal (atropine/ scopolamine/ hyoscyamine/ phenobarbital), Levsin/Levsinex (hyoscyamine), Ditropan (oxybutynin), Enablex (darifenacin), or VESIcare (solifenacin)]

AND

3 - Patient is routinely performing clean intermittent self-catheterization (CIC) or is willing/able to perform CIC if he/she has post-void residual (PVR) urine volume greater than 200 mL

AND

4 - Prescribed by or in consultation with a urologist

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Migraine
Approval Length	3 Month [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Diagnosis of chronic migraines [I]

AND

2 - Patient has greater than or equal to 8 migraine days per month [1, 13-16, L]

AND

3 - Patient is 18 years of age or older [N]

AND

4 - Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [M]

AND

5 - History of failure (after at least a two month trial), contraindication or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action: [H, J, O, P, Q, R]

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, metoprolol
- Candesartan
- Lisinopril

AND

6 - Trial and failure, contraindication or intolerance to one of the following:

- Aimovig
- Ajovy

AND

7 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain specialist
- Headache specialist

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Migraine
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand

BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines) [19]

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of therapy

AND

3 - At least 3 months have or will have elapsed since the last series of injections

AND

4 - Patient continues to be monitored for medication overuse headache (MOH) [M]

AND

5 - Trial and failure, contraindication or intolerance to one of the following:

- Aimovig
- Ajovy

AND

6 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain specialist

- Headache specialist

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Spasticity
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of upper limb spasticity

AND

1.1.2 Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport

OR

1.2 Both of the following:

1.2.1 Diagnosis of lower limb spasticity

AND

1.2.2 Trial and failure, contraindication or intolerance to Dysport

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Upper Limb Spasticity
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Lower Limb Spasticity
Approval Length	3 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - Trial and failure, contraindication or intolerance to Dysport

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Cervical Dystonia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis)

AND

2 - Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport
- Myobloc

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Cervical Dystonia
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport

- Myobloc

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Primary Axillary Hyperhidrosis
Approval Length	1 Time(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Diagnosis of primary axillary hyperhidrosis [G]

AND

2 - One of the following:

2.1 Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) [A, 1, 4]

OR

2.2 Skin maceration with secondary infection [5]

AND

3 - Trial and failure, contraindication, or intolerance to topical prescription strength drying agents [e.g., Drysol, Hypercare, Xerac AC (aluminum chloride hexahydrate)]

Product Name:Botox (Excluded: Botox Cosmetic)

Diagnosis	Primary Axillary Hyperhidrosis
Approval Length	1 Time(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - At least a 2-point improvement in HDSS [1, 4]

AND

2 - At least 3 months have or will have elapsed since the last series of injections [1, 4]

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Blepharospasm, Strabismus, VII Cranial Nerve Disorders
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - One of the following:

1.1 One of the following:

1.1.1 All of the following:

1.1.1.1 Diagnosis of blepharospasm associated with dystonia (e.g., benign essential blepharospasm)

AND

1.1.1.2 Patient is 18 years of age or older

AND

1.1.1.3 Trial and failure, contraindication or intolerance to Xeomin

OR

1.1.2 Patient is 12 thru 17 years of age

OR

1.2 Diagnosis of strabismus

OR

1.3 Diagnosis of VII cranial nerve disorders (hemifacial spasms)

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Blepharospasm
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand

BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - One of the following:

3.1 Both of the following:

- Patient is 18 years of age or older
- Trial and failure, contraindication or intolerance to Xeomin

OR

3.2 Patient is 12 thru 17 years of age

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Adult Bladder Dysfunction, Strabismus, VII Cranial Nerve Disorders
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Anal Fissure (Off-Label)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Diagnosis of chronic anal fissure [8, 9]

AND

2 - At least 2 months of one of the following symptoms:

- Nocturnal pain and bleeding
- Postdefecation pain

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies:

- Topical nitrates (e.g. Glyceryl trinitrate (Nitroglycerin))
- Topical calcium channel blockers (CCBs) (e.g., diltiazem, nifedipine)

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Anal Fissure (Off-Label)
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - One of the following:

- Incomplete healing of fissure
- Recurrence of fissure

AND

2 - Patient demonstrates positive clinical response to therapy

AND

3 - At least 3 months have or will have elapsed since the last series of injections

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Back Pain [D] (Off-Label)

Approval Length	1 treatment session (series of injections) [K]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Diagnosis of low back pain

AND

2 - Low back pain has lasted for greater than or equal to six (6) months

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Neurosurgeon
- Orthopedist
- Pain specialist

AND

4 - Trial and failure (at least 3 months), contraindication, or intolerance to both of the following conventional therapies: [10-12]

- At least one oral NSAID medication
- At least one opioid medication

AND

5 - Trial and failure or inadequate response to one of the following: [10]

- Physical therapy
- Nonpharmacologic therapy (e.g., spinal manipulation, massage therapy, transcutaneous electrical nerve stimulation (TENS), acupuncture/acupressure, and surgery)

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Back Pain [D] (Off-Label)
Approval Length	1 treatment session (series of injections) [K]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last series of injections

AND

3 - Treatment has not exceeded two treatment sessions total per year

Notes	Authorization will not exceed more than two treatment sessions total per year (including initial authorization).

Product Name:Botox (Excluded: Botox Cosmetic)

Diagnosis	Achalasia (Off-Label)
Approval Length	6 Month(s) [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Diagnosis of achalasia

AND

2 - One of the following:

2.1 High risk of complication from or failure to one of the following: [6, 7]

- Pneumatic dilation
- Myotomy

OR

2.2 Prior dilation caused esophageal perforation

OR

2.3 Patient has an increased risk of dilation-induced perforation due to one of the following:

- Epiphrenic diverticulum
- Hiatal hernia

Product Name:Botox (Excluded: Botox Cosmetic)

Diagnosis	Achalasia (Off-Label)
Approval Length	6 Month [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (i.e., improvement or reduction in symptoms of dysphagia, regurgitation, chest pain)

AND

2 - At least 6 months have or will have elapsed since the last series of injections [C]

Product Name:Botox (Excluded: Botox Cosmetic)	
Diagnosis	All other diagnoses
Approval Length	6 months unless the FDA-approved treatment duration is less than 6 months. If FDA-approved treatment duration is less than 6 months, utilize the FDA-approved duration for authorization period.
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.2 Additional requirements listed in the “Indications and Usage” and “Dosage and Administration” sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc)

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - Trial and failure, contraindication, or intolerance to two appropriate formulary alternatives (if available)

Product Name:All Products	
Diagnosis	Cosmetic Use
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BOTOX	ONABOTULINUMTOXINA FOR INJ 100 UNIT	74400020052120	Brand
BOTOX	ONABOTULINUMTOXINA FOR INJ 200 UNIT	74400020052140	Brand
BOTOX COSMETIC	ONABOTULINUMTOXINA (COSMETIC) FOR INJ 50 UNIT	90890020002110	Brand
BOTOX COSMETIC	ONABOTULINUMTOXINA (COSMETIC) FOR INJ 100 UNIT	90890020002120	Brand

Approval Criteria

1 - Requests for coverage of any Botox product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only.

3 . Endnotes

A. Hyperhidrosis Disease Severity Scale • The HDSS is a 4-point scale designed to assess the severity of hyperhidrosis in everyday clinical practice or in clinical research and the effectiveness of treatment. • The HDSS can be administered by an interviewer or self-completed by the patient. • The HDSS assess disease severity based on the extent of sweating-related impairment of daily activities. (1) Question - My (underarm) sweating is never noticeable and never interferes with my daily activities, Score - 1; (2) Question - My (underarm) sweating is tolerable but sometimes interferes with my daily activities, Score - 2; (3) Question - My (underarm) sweating is barely tolerable and frequently interferes with my daily activities, Score - 3; (4) Question - My (underarm) sweating is intolerable and always interferes with my daily activities, Score - 4

B. This recommendation is based on results from the PREEMPT 2 trial. The primary endpoint of PREEMPT 2 was the mean change from baseline in frequency of headache days for the 28-day period ending with week 24. [13, 14]

C. Approximately 50% of achalasia patients relapse and require repeat treatments at 6 to 24-month intervals. [6]

D. An evidence-based review by the American Academy of Neurology (AAN) concluded that botulinum neurotoxin (BoNT) is possibly effective for the treatment of chronic predominantly unilateral low back pain (LBP) [one Class II study]. The AAN recommends that BoNT may be considered as a treatment option for patients with chronic predominantly unilateral LBP (Level C). [12]

E. An evidence-based review by the AAN established BoNT as safe and effective for the treatment of neurogenic detrusor overactivity (NDO) in adults (one Class I study and one Class II study). Data on the use of BoNT is probably safe and effective for the treatment of detrusor sphincter dyssynergia (DSD) in patients with spinal cord injury (2 Class II studies). On basis of one Class I study, BoNT does not provide significant benefit for the treatment of DSD in patients with multiple sclerosis (MS). The AAN recommends that BoNT should be offered as a treatment option for neurogenic detrusor overactivity (Level A), and that BoNT should be considered for DSD in patients with spinal cord injury (Level B). [12]

F. BoNT is not effective in patients with DSD due to multiple sclerosis in a multicenter, double-blind, placebo-controlled trial; however, in patients with DSD due to spinal cord injury, open-label clinical studies showed improvements in urodynamic parameters [recommendation for DSD: Adult, Class IIb, Category B]. For NDO, the use of BoNT (refractory to antispasmodics) in a randomized, double-blind, placebo-controlled clinical trial of 59 patients (n = 53 with spinal cord injury and n = 6 with multiple sclerosis) showed significant improvement in daily incontinence episodes in weeks 1 through 24 (except for weeks 12 and 18) compared to placebo [recommendation for NDO: Adult, Class IIb, Category B]. [12]

G. The safety and effectiveness of Botox for hyperhidrosis in areas other than the axillae have not been established. [1]

H. Clinical benefit from prophylactic therapy may take as long as 2 to 3 months to manifest. [17, 18] Recommended first-line agents for the prevention of migraine headache are atenolol, nadolol, propranolol, timolol, amitriptyline, venlafaxine, topiramate, divalproex sodium, and sodium valproate. [17]

I. Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies. [1] An evidence-based review by the American Academy of Neurology determined that, based on available evidence, Botox was probably ineffective in episodic migraine and tension-type headaches, and should not be considered in patients with these conditions. [12]
J. The effects of Botox in reducing the frequency of headache days in the PREEMPT trial and in the pooled analysis of the PREEMPT trials were very modest. Given the experience and evidence we have for other prophylactic treatments in the management of migraine, which are supported by national guidelines, it is reasonable to require failure with other prophylactic treatments before approving use of Botox. [17]
K. A single small randomized trial (n = 31) compared paravertebral injections of botulinum toxin with saline injections and found significant benefit of botulinum toxin up to eight weeks after injection. There is currently no consensus on number of injections or treatment length for low back pain. [12]
L. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [20]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.
M. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [20]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
N. The safety and effectiveness of Botox for chronic headache in patients below the age of 18 years have not been established. In a 12-week, multicenter, double-blind, placebo-controlled clinical trial, 123 adolescent patients (ages 12 to below 18 years) with chronic migraine were randomized to receive Botox 74 Units, Botox 155 Units, or placebo, for one injection cycle. This trial did NOT establish the efficacy of Botox, compared with placebo, for the prophylaxis of headaches in adolescents with chronic migraine. [1]
O. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], and beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol] [21]. They also support the use of Botox (onabotulinumtoxin A) as an efficacious treatment option for chronic migraine. Botox (onabotulinumtoxin A) is not however recommended for episodic migraine treatment.
P. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [17]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
Q. The OptumRx clinical team consulted with a neurologist [22]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more on patient specific factors.
R. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after

failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [23].

4 . References

1. Botox Prescribing Information. Allergan, Inc. Madison, NJ. November 2023.
2. AHFS Drug Information (2005) website. Available at: http://online.lexi.com/lco/action/doc/retrieve/docid/pdh_f/130028?searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3DBotox%26t%3Dname%26va%3DBotox. Accessed June 13, 2023.
3. DRUGDEX System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Accessed June 13, 2023.
4. Lowe NJ, Glaser DA, Eadie N, Daggett S, Kowalski JW, Lai PY. Botulinum toxin type A in the treatment of primary axillary hyperhidrosis: a 52-week multicenter double-blind, randomized, placebo-controlled study of efficacy and safety. J Am Acad Dermatol. 2007;56:604-611.
5. Naumann M, Lowe NJ. Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: randomised, parallel group, double blind, placebo controlled trial. BMJ 2001;323:596-9.
6. Vaezi MF, Pandolfino JE, Vela MF. American College of Gastroenterology Practice Parameter Committee. Diagnosis and management of achalasia. Am J Gastroenterol advance online publication, 23 July 2013.
7. Pasricha PJ, et al. Intrasphincteric botulinum toxin for the treatment of achalasia. N Engl J Med 1995;332:774-8.
8. American Society of Colon and Rectal Surgeons. Practice Parameters for the Management of Anal Fissures (3rd Revision). Dis Colon Rectum 2010; 53: 1110–1115.
9. Brisinda G, et al. A comparison of injections of botulinum toxin and topical nitroglycerin ointment for the treatment of chronic anal fissure. N Engl J Med 1999;341:65-9.
10. Ney JP, Difazio M, Sichani A, Monacci W, Foster L, Jabbari B. Treatment of chronic low back pain with successive injections of botulinum toxin A over 6 months: a prospective trial of 60 patients. Clin J Pain 2006;22(4):363-369.
11. MayoClinic. Back pain. Available at: www.mayoclinic.com. Accessed June 13, 2023.
12. Naumann M, So Y, Argoff CE et al. Assessment: botulinum neurotoxin in the treatment of autonomic disorder and pain (an evidence-based review): report of the Therapeutics and Assessment Subcommittee of the American Academy of Neurology. Neurology 2008;70:1707-1714.
13. Aurora SK, Dodick DW, Turkel CC, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 1 trial. Cephalagia. 2010;30:793-803.
14. Diener HC, Dodick DW, Aurora SK, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. Cephalagia. 2010;30:804-814.
15. Dodick DW, Turkel CC, DeGryse RE, et al. OnabotulinumtoxinA for treatment of chronic migraine: pooled results from the double-blind, randomized, placebo-controlled phases of the PREEMPT clinical program. Headache. 2010;50:921-936.
16. Per clinical consultation with neurologist, January 7, 2011.
17. Silberstein SD, Holland S, Freitag F, et al; Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Evidence-based

guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology 2012 Apr 24;78(17):1337-45.
18. Loder E, Burch R, Rizzoli P.The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A Summary and Comparison With Other Recent Clinical Practice Guidelines. Headache 2012;52:930-945.
19. Per clinical consultation with neurologist, July 20, 2015.
20. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition (beta version). Cephalalgia. 2013; 33: 629-808.
21. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26.
22. Per Clinical Consultation with a Neurologist. January 24th, 2018.
23. National Institute for Health and Care Excellence. Management of migraine (with or without aura). April 17th, 2018. Available at: https://pathways.nice.org.uk/pathways/headaches/management-of-migraine-with-or-without-aura#path=view%3A/pathways/headaches/management-of-migraine-with-or-without-aura.xml&content=view-node%3Anodes-prophylactic-treatment. Accessed August 14, 2020.
24. Botox Cosmetic Prescribing Information. Allergan, Inc. Irvine, CA. November 2023.

5 . Revision History

Date	Notes
2/18/2025	Quartz commercial copied to OptumRx

Prior Authorization Guideline

Guideline ID	GL-228774
Guideline Name	BPH Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cardura XL (doxazosin mesylate extended-release)
Benign prostatic hyperplasia (BPH) Indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Cardura XL is NOT indicated for the treatment of hypertension.
Drug Name: Entadfi (finasteride and tadalafil)
Benign prostatic hyperplasia (BPH) Indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks. Limitations of Use: Entadfi is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is unknown.

2 . Criteria

Product Name:Cardura XL	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
CARDURA XL	DOXAZOSIN MESYLATE TAB SR 24 HR 4 MG (BASE EQUIV)	56852025207520	Brand
CARDURA XL	DOXAZOSIN MESYLATE TAB SR 24 HR 8 MG (BASE EQUIV)	56852025207530	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (minimum 30 days supply), contraindication, or intolerance to any TWO of the following generics: [2]

- alfuzosin
- doxazosin
- tamsulosin
- terazosin
- silodosin

Product Name:Entadfi	
Approval Length	26 weeks [A, 2]
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ENTADFI	FINASTERIDE-TADALAFIL CAP 5-5 MG	56859902300120	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (minimum 30 days supply), contraindication, or intolerance to any ONE of the following generics: [B, 3]

- alfuzosin
- doxazosin
- tamsulosin
- terazosin
- silodosin

AND

3 - Trial and failure, contraindication, or intolerance to any ONE of the following:

- 5-alpha-reductase inhibitor (i.e., finasteride, dutasteride)
- phosphodiesterase type 5 inhibitor (i.e., tadalafil 5 mg)

3 . Endnotes

A. Limitations of Use: Entadfi is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is unknown. [2]
B. Attempts to identify subgroups of patients who may respond better to one alpha- blocker or another have not shown differences in efficacy. Given that medication type and patient characteristics do not impact effectiveness, it is not recommended to switch between various options for insufficient response. However, changing from one alpha- blocker to another on the basis of a side effect is worthwhile. [3]

4 . References

1. Cardura XL prescribing information. Pfizer, Inc. New York, New York. June 2021.
2. Entadfi prescribing information. Veru Inc. Miami, FL. December 2021.
3. The American Urological Association. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART I—Initial Work-up

and Medical Management. Guideline 2021. Available at: https://www.auajournals.org/doi/10.1097/JU.0000000000002183. Accessed September 9, 2022.

Braftovi (encorafenib)

Prior Authorization Guideline

Guideline ID	GL-228376
Guideline Name	Braftovi (encorafenib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Braftovi (encorafenib)
BRAF V600E or V600K unresectable or metastatic melanoma Indicated in combination with Mektovi (binimetinib) for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutation, as detected by an FDA-approved test. Limitations of Use: Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF CRC, or wild-type BRAF NSCLC. **BRAF V600E Mutation-Positive Metastatic Colorectal Cancer (CRC)** Indicated in combination with Erbitux (cetuximab) for the treatment of adult patients with metastatic colorectal cancer with BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy. Limitations of Use: Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF CRC, or wild-type BRAF NSCLC. **BRAF V600E Mutation-Positive Metastatic Non-Small Cell Lung Cancer (NSCLC)** Indicated in combination with Mektovi (binimetinib) for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test. Limitations of use: Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF CRC, or wild-type BRAF NSCLC.

2 . Criteria

Product Name:Braftovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRAFTOVI	ENCORAFENIB CAP 75 MG	21532040000130	Brand

Approval Criteria

1 - One of the following diagnoses: [2]

- Unresectable melanoma
- Metastatic melanoma

AND

2 - Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Used in combination with Mektovi (binimetinib)

AND

4 - One of the following:

4.1 Trial and failure, contraindication or intolerance to one of the following:

- Zelboraf (vemurafenib)
- Tafinlar (dabrafenib)

OR

4.2 For continuation of prior therapy

Product Name:Braftovi	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRAFTOVI	ENCORAFENIB CAP 75 MG	21532040000130	Brand

Approval Criteria

1 - One of the following diagnoses:

- Colon Cancer
- Rectal Cancer

AND

2 - One of the following [3,4]:

- Unresectable or advanced disease
- Metastatic disease

AND

3 - Patient has received prior therapy

AND

4 - Cancer is BRAFV600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Used in combination with Erbitux (cetuximab)

Product Name:Braftovi	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRAFTOVI	ENCORAFENIB CAP 75 MG	21532040000130	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Used in combination with Mektovi (binimetinib)

Product Name:Braftovi	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRAFTOVI	ENCORAFENIB CAP 75 MG	21532040000130	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Braftovi Prescribing Information. Array Biopharma Inc. Boulder, CO. October 2023.
2. National Comprehensive Cancer Network. Clinical practice guidelines in oncology: melanoma cutaneous v.3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed June 1, 2022.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Colon Cancer. Version 1.2022. Accessed June 5, 2023.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer. Version 1.2022. http://www.nccn.org/professionals/physician_gls/PDF/rectal.pdf. Accessed June 5, 2023.

Prior Authorization Guideline

Guideline ID	GL-228377
Guideline Name	Brand Estradiol Transdermal Systems
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Minivelle (estradiol transdermal system)
Moderate to Severe Vasomotor Symptoms Indicated for the treatment of moderate to severe vasomotor symptoms due to menopause. **Prevention of Postmenopausal Osteoporosis** Indicated for the prevention of postmenopausal osteoporosis. Limitation of Use: When prescribing solely for the prevention of postmenopausal osteoporosis, first consider the use of non-estrogen medications. Consider estrogen therapy only for women at significant risk of osteoporosis.
Drug Name: Menostar (estradiol transdermal system)
Prevention of Postmenopausal Osteoporosis Indicated for the prevention of postmenopausal osteoporosis. Limitation of Use: When prescribing solely for the prevention of postmenopausal osteoporosis, first consider the use of non-estrogen medications. Consider estrogen therapy only for women at significant risk of osteoporosis.
Drug Name: Alora (estradiol transdermal system)

Moderate to Severe Vasomotor Symptoms Indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

Moderate to Severe Symptoms of Vulvar and Vaginal Atrophy Indicated for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause. Limitation of Use: When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, first consider the use of topical vaginal products.

Hypoestrogenism Indicated for the treatment of hypoestrogenism due to hypogonadism, castration or primary ovarian failure.

Prevention of Postmenopausal Osteoporosis Indicated for the prevention of postmenopausal osteoporosis. Limitation of Use: When prescribing solely for the prevention of postmenopausal osteoporosis, only consider therapy for women at significant risk of osteoporosis. First consider the use of non-estrogen medications.

Drug Name: Vivelle-Dot (estradiol transdermal system)

Moderate to Severe Vasomotor Symptoms Indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

Moderate to Severe Symptoms of Vulvar and Vaginal Atrophy Indicated for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause. Limitations of Use: When prescribing solely for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy, first consider the use of topical vaginal products.

Hypoestrogenism Indicated for the treatment of hypoestrogenism due to hypogonadism, castration, or primary ovarian failure.

Prevention of Postmenopausal Osteoporosis Indicated for the prevention of postmenopausal osteoporosis. Limitations of Use: When prescribing solely for the prevention of postmenopausal osteoporosis, first consider the use of non-estrogen medications. Consider estrogen therapy only for women at significant risk of osteoporosis.

2 . Criteria

Product Name:Minivelle, Menostar, Alora, Vivelle-Dot	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic

MINIVELLE	ESTRADIOL TD PATCH TWICE WEEKLY 0.025 MG/24HR	24000035008705	Brand
ALORA	ESTRADIOL TD PATCH TWICE WEEKLY 0.025 MG/24HR	24000035008705	Brand
MINIVELLE	ESTRADIOL TD PATCH TWICE WEEKLY 0.0375 MG/24HR	24000035008710	Brand
MINIVELLE	ESTRADIOL TD PATCH TWICE WEEKLY 0.05 MG/24HR	24000035008720	Brand
MINIVELLE	ESTRADIOL TD PATCH TWICE WEEKLY 0.075 MG/24HR	24000035008730	Brand
ALORA	ESTRADIOL TD PATCH TWICE WEEKLY 0.075 MG/24HR	24000035008730	Brand
MENOSTAR	ESTRADIOL TD PATCH WEEKLY 14 MCG/24HR	24000035008805	Brand
MINIVELLE	ESTRADIOL TD PATCH TWICE WEEKLY 0.1 MG/24HR	24000035008750	Brand
ALORA	ESTRADIOL TD PATCH TWICE WEEKLY 0.1 MG/24HR	24000035008750	Brand
VIVELLE-DOT	ESTRADIOL TD PATCH TWICE WEEKLY 0.025 MG/24HR	24000035008705	Brand
VIVELLE-DOT	ESTRADIOL TD PATCH TWICE WEEKLY 0.0375 MG/24HR	24000035008710	Brand
VIVELLE-DOT	ESTRADIOL TD PATCH TWICE WEEKLY 0.05 MG/24HR	24000035008720	Brand
VIVELLE-DOT	ESTRADIOL TD PATCH TWICE WEEKLY 0.075 MG/24HR	24000035008730	Brand
VIVELLE-DOT	ESTRADIOL TD PATCH TWICE WEEKLY 0.1 MG/24HR	24000035008750	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 28-day supply or intolerance to generic estradiol patch

3 . References

1. Minivelle Prescribing Information. Noven Pharmaceuticals Inc. Miami, FL. February 2024.

2. Menostar Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. December 2023.
3. Alora Prescribing Information. Allergan USA, Inc. Madison, NJ. March 2020.
4. Vivelle-Dot Prescribing Information. Sandoz Inc. Princeton, NJ. November 2023.

Prior Authorization Guideline

Guideline ID	GL-228380
Guideline Name	Brukinsa (zanubrutinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Brukinsa (zanubrutinib)
Mantle Cell Lymphoma Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. **Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma** Indicated for the treatment of adult patients with Waldenström’s macroglobulinemia (WM)/ Lymphoplasmacytic Lymphoma [6] **Marginal Zone Lymphoma** Indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma** Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic

lymphoma (SLL).

Follicular Lymphoma Indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 . Criteria

Product Name:Brukinsa	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRUKINSA	ZANUBRUTINIB CAP 80 MG	21532195000120	Brand

Approval Criteria

1 - Diagnosis of relapsed or refractory mantle cell lymphoma (MCL)

AND

2 - Patient has received at least one prior therapy for MCL (e.g., chemotherapy)

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to one of the following:

- Calquence (acalabrutinib)

- Imbruvica (ibrutinib)

OR

3.2 For continuation of prior therapy

Product Name:Brukinsa	
Diagnosis	Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRUKINSA	ZANUBRUTINIB CAP 80 MG	21532195000120	Brand

Approval Criteria

1 - Diagnosis of Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma [6]

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to one of the following:

- Calquence (acalabrutinib)
- Imbruvica (ibrutinib)

OR

2.1 For continuation of prior therapy

Product Name:Brukinsa

Diagnosis	Marginal Zone Lymphoma (MZL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRUKINSA	ZANUBRUTINIB CAP 80 MG	21532195000120	Brand

Approval Criteria

1 - Diagnosis of Marginal Zone Lymphoma (MZL)

AND

2 - Disease is relapsed or refractory

AND

3 - Patient has received at least one anti-CD20-based regimen for MZL (e.g., rituximab, obinutuzumab)

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to one of the following:

- Calquence (acalabrutinib)
- Imbruvica (ibrutinib)

OR

4.2 For continuation of prior therapy

Product Name:Brukinsa	
Diagnosis	Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRUKINSA	ZANUBRUTINIB CAP 80 MG	21532195000120	Brand

Approval Criteria

1 - Diagnosis of ONE of the following:

- Chronic Lymphocytic Leukemia (CLL)
- Small Lymphocytic Lymphoma (SLL)

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to one of the following:

- Calquence (acalabrutinib)
- Imbruvica (ibrutinib)

OR

2.2 For continuation of prior therapy

Product Name:Brukinsa	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRUKINSA	ZANUBRUTINIB CAP 80 MG	21532195000120	Brand

Approval Criteria

1 - Diagnosis of follicular lymphoma (FL)

AND

2 - Disease is relapsed or refractory

AND

3 - Used in combination with Gazyva (obinutuzumab)

AND

4 - Patient has received at least two prior lines of systemic therapy including both of the following:

- An anti-CD20 antibody [e.g., rituximab]
- An approved alkylator-based combination therapy [e.g., bendamustine in combination with obinutuzumab or rituximab, CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)]

Product Name:Brukinsa	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

BRUKINSA	ZANUBRUTINIB CAP 80 MG	21532195000120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Chemotherapy regimens may include bendamustine; cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP); cyclophosphamide, vincristine, prednisone (CVP); fludarabine, cyclophosphamide, mitoxantrone (FCM).

4 . References

1. Brukinsa Prescribing Information. BeiGene USA, Inc. San Mateo, CA. March 2024.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. B-Cell Lymphomas v4.2020. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. (Accessed March 26, 2024).
3. ClinicalTrials.gov [Internet]. U.S. National Library of Medicine. Identifier NCT02343120. Study of the Safety and Pharmacokinetics of BGB-3111 in Subjects With B-Cell Lymphoid Malignancies; January 21, 2015. Available from: https://clinicaltrials.gov/ct2/show/NCT02343120.
4. ClinicalTrials.gov [Internet]. U.S. National Library of Medicine. Identifier NCT03206970. Study of Evaluate Efficacy and Safety of BGB-3111 in Subjects With Relapsed or Refractory Mantle Cell Lymphoma (MCL); July 2, 2017. Available from: https://clinicaltrials.gov/ct2/show/results/NCT03206970.
5. Schulz H, Bohlius J, Trelle S et al. Immunochemotherapy With Rituximab and Overall Survival in Patients With Indolent or Mantle Cell Lymphoma: A Systematic Review and Meta-analysis. JNCI Journal of the National Cancer Institute. 2007;99(9):706-714. doi:10.1093/jnci/djk152.
6. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Waldenström's macroglobulinemia/Lymphoplasmacytic Lymphoma. V1.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf. Accessed September 15, 2021.
7. Tam CS, Opat S, D'Sa S, et al. A randomized phase 3 trial of zanubrutinib vs ibrutinib in symptomatic Waldenström macroglobulinemia: the ASPEN study. Blood. 2020;136(18):2038-2050. doi:10.1182/blood.2020006844
8. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. B-Cell Lymphomas. V1.2024. Available by subscription at:

https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed Match 26, 2024.

Prior Authorization Guideline

Guideline ID	GL-228381
Guideline Name	Bylvay (odevixibat)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Bylvay (odevixibat)
Pruritus associated with progressive familial intrahepatic cholestasis (PFIC) Indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Limitation of Use: Bylvay may not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3). **Alagille syndrome** Indicated for the treatment of cholestatic pruritus in patients 12 months of age and older with Alagille syndrome.

2 . Criteria

Product Name:Bylvay

Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BYLVAY	ODEVIXIBAT CAP 400 MCG	52350060000120	Brand
BYLVAY	ODEVIXIBAT CAP 1200 MCG	52350060000140	Brand
BYLVAY (PELLETS)	ODEVIXIBAT PELLETS CAP SPRINKLE 200 MCG	52350060006810	Brand
BYLVAY (PELLETS)	ODEVIXIBAT PELLETS CAP SPRINKLE 600 MCG	52350060006830	Brand

Approval Criteria

1 - Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3 confirmed by one of the following: [B-D, 2]

- Diagnostic test (e.g., liver function test, liver ultrasound and biopsy, bile analysis)
- Genetic Testing

AND

2 - Patient is experiencing both of the following: [1]

- Moderate to severe pruritus
- Patient has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory

AND

3 - Patient is 3 months of age or older

AND

4 - Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: [6]

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Prescribed by or in consultation with a hepatologist or gastroenterologist

Product Name:Bylvay	
Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BYLVAY	ODEVIXIBAT CAP 400 MCG	52350060000120	Brand
BYLVAY	ODEVIXIBAT CAP 1200 MCG	52350060000140	Brand
BYLVAY (PELLETS)	ODEVIXIBAT PELLETS CAP SPRINKLE 200 MCG	52350060006810	Brand
BYLVAY (PELLETS)	ODEVIXIBAT PELLETS CAP SPRINKLE 600 MCG	52350060006830	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduced serum bile acids, improved pruritus)

Product Name:Bylvay	
Diagnosis	Alagille Syndrome (ALGS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BYLVAY	ODEVIXIBAT CAP 400 MCG	52350060000120	Brand
BYLVAY	ODEVIXIBAT CAP 1200 MCG	52350060000140	Brand
BYLVAY (PELLETS)	ODEVIXIBAT PELLETS CAP SPRINKLE 200 MCG	52350060006810	Brand
BYLVAY (PELLETS)	ODEVIXIBAT PELLETS CAP SPRINKLE 600 MCG	52350060006830	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Alagille Syndrome (ALGS)

AND

1.2 Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene [E, 7, 9]

AND

2 - Patient is experiencing both of the following: [10]

- Moderate to severe cholestatic pruritus
- Patient has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory

AND

3 - Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: [F, 7-8]

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

4 - Patient is 12 months of age or older

AND

5 - Prescribed by or in consultation with a hepatologist or gastroenterologist

Product Name:Bylvay	
Diagnosis	Alagille Syndrome (ALGS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BYLVAY	ODEVIXIBAT CAP 400 MCG	52350060000120	Brand
BYLVAY	ODEVIXIBAT CAP 1200 MCG	52350060000140	Brand
BYLVAY (PELLETS)	ODEVIXIBAT PELLETS CAP SPRINKLE 200 MCG	52350060006810	Brand
BYLVAY (PELLETS)	ODEVIXIBAT PELLETS CAP SPRINKLE 600 MCG	52350060006830	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score)

3 . Definitions

Definition	Description
PFIC	PFIC:[2] Progressive: tending to get worse over time; Familial: originally described in families and related to changes in genes;

	Intrahepatic: involves disease inside the liver; Cholestasis: means poor bile flow and build-up of substances in the liver that would normally be carried out of the liver into bile and then the intestines

4 . Endnotes

A. If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg [3].
B. The efficacy of BYLVAY was evaluated in Trial 1 (NCT03566238), a 24-week, randomized, double-blind, placebo-controlled trial. Trial 1 was conducted in 62 pediatric patients, aged 6 months to 17 years, with a confirmed molecular diagnosis of PFIC type 1 or type 2, and presence of pruritus at baseline. [3]
C. Trial 2 is a 72-week, open-label, single-arm trial in PFIC type 1, 2, and 3 patients. [3]
D. Diagnostic testing may include liver functions tests, liver ultrasound and biopsy, and/or bile analysis. Genetic testing may be used in selected patients to confirm diagnosis and distinguish type. All 3 subtypes of PFIC have increased serum bile acid levels. [5]
E. Alagille Syndrome is an autosomal dominant disease with variable expressivity, caused by heterozygous mutations in either JAG1 or NOTCH2. The vast majority of cases are due to JAG1 mutations accounting for 94%, and NOTCH2 mutations in additional 2–4%. [7]
F. The management of pruritus in ALGS is challenging, and a variety of therapies are often used. These include antihistamines, rifampin, ursodeoxycholic acid, cholestyramine, naltrexone, and sertraline. Clinical experience suggests that these drugs have variable efficacy in reducing pruritus; however, no prospective clinical trials has quantified the effect of any of these therapies, either alone or in combination. [8]

5 . References

1. Bylvay (odevixibat) [prescribing information]. Albireo Pharma Inc. Boston, MA. June 2023.
2. PFIC Advocacy and Resource Network, Inc. Available at https://www.pfic.org/types-and-subtypes-of-pfic/ Accessed August 5, 2021.
3. Bylvay (odevixibat) [prescribing information]. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215498s000lbl.pdf?utm_medium=email&utm_source=govdelivery. Accessed August 5, 2021.
4. Lexicomp [database online]. Available at www.uptodate.com/contents/odevixibat-drug-information?search=bylvay&source=panel_search_result&selectedTitle=1~1&usage_type=panel&kp_tab=drug_general&display_rank=1. Last accessed August 5, 2021.
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7. Ayoub MD, Kamath BM. Alagille Syndrome: Diagnostic Challenges and Advances in Management. Diagnostics (Basel). 2020;10(11):907. Published 2020 Nov 6. doi:10.3390/diagnostics10110907
8. Shneider BL, Spino C, Kamath BM, et al. Placebo-Controlled Randomized Trial of an Intestinal Bile Salt Transport Inhibitor for Pruritus in Alagille Syndrome. Hepatol Commun. 2018;2(10):1184-1198.
9. Diaz-Frias J, Kondamudi NP. Alagille Syndrome. [Updated 2021 Jun 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK507827/
10. ClinicalTrials.gov: Available at: https://www.clinicaltrials.gov/study/NCT04674761?term=NCT04674761&rank=1. Accessed July 12, 2023.
11. Saleh M, Kamath BM, Chitayat D. Alagille syndrome: clinical perspectives. Appl Clin Genet. 2016;9:75-82. Published 2016 Jun 30. doi:10.2147/TACG.S86420

Prior Authorization Guideline

Guideline ID	GL-228803
Guideline Name	Cablivi (caplacizumab-yhdp)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cablivi (caplacizumab-yhdp)
Acquired Thrombotic Thrombocytopenic Purpura (aTTP) Indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

2 . Criteria

Product Name:Cablivi	
Diagnosis	Acquired Thrombotic Thrombocytopenic Purpura (aTTP)
Approval Length	3 Months [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABLIVI	CAPLACIZUMAB-YHDP FOR INJ KIT 11 MG	85151020806420	Brand

Approval Criteria

1 - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)

AND

2 - First dose was/will be administered by a healthcare provider as a bolus intravenous injection

AND

3 - Used in combination with immunosuppressive therapy (e.g., rituximab, glucocorticoids) [3]

AND

4 - One of the following:

4.1 Used in combination with plasma exchange

OR

4.2 Both of the following:

- Patient has completed plasma exchange
- Less than 59 days have or will have elapsed beyond the last plasma exchange [B]

AND

5 - Prescribed by or in consultation with a hematologist or oncologist[2]

3 . Endnotes

A. Three month approval duration, based on package insert stating longest therapy in trial was 77 days.
B. Per package insert, after the plasma exchange period can use injection once daily for 30 days beyond the last plasma exchange and after the initial treatment course, if signs of persistent underlying disease are present treatment can be extended for a maximum of 28 days, totaling 58 days of therapy after last plasma exchange.

4 . References

1. Cablivi Prescribing Information. Cambridge, MA. Genzyme Corporation. April 2023
2. Understanding TTP. https://www.understandingttp.com/patient/ttp-treatment/#overview-of-treatment. Accessed January 28, 2021.
3. FDA News Release: FDA approves first therapy for the treatment of adult patients with a rare blood clotting disorder. U.S. Food and Drug Administration; February 6, 2019. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630851.htm. Accessed January 28, 2021.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228805
Guideline Name	Cabometyx (cabozantinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cabometyx (cabozantinib) tablets
Renal cell carcinoma (RCC) Indicated for the treatment of patients with advanced renal cell carcinoma (RCC). **Renal cell carcinoma (RCC)** Indicated, in combination with nivolumab, for the first-line treatment of patients with advanced RCC. **Hepatocellular Carcinoma (HCC)** Indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. **Differentiated Thyroid Cancer** Indicated for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.

2 . Criteria

Product Name:Cabometyx	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABOMETYX	CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)	21533010100320	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)	21533010100330	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)	21533010100340	Brand

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Cabometyx	
Diagnosis	Hepatocellular Carcinoma (HCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABOMETYX	CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)	21533010100320	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)	21533010100330	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)	21533010100340	Brand

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma (HCC)

AND

2 - Trial and failure, contraindication, or intolerance to Nexavar (sorafenib tosylate)*

Notes	*Criterion is part of the FDA-approved label. If patient meets criteria a bove, please approve at GPI-12.

Product Name:Cabometyx	
Diagnosis	Differentiated Thyroid Cancer (DTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABOMETYX	CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)	21533010100320	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)	21533010100330	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)	21533010100340	Brand

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC) [A, 5]

AND

2 - Patient is 12 years of age or older

AND

3 - Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib])*

AND

4 - Disease or patient is refractory to radioactive iodine treatment or ineligible

Notes	*Criterion is part of the FDA-approved label. If patient meets criteria a bove, please approve at GPI-12.

Product Name:Cabometyx	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABOMETYX	CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)	21533010100320	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)	21533010100330	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)	21533010100340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	If patient meets criteria above, please approve at GPI-12.

3 . Endnotes

A. Differentiated thyroid carcinomas are broadly categorized as papillary thyroid carcinoma (PTC), follicular cancer (FTC), and Hurthle cell carcinoma (HCTC). [3]

4 . References

1. Cabometyx Prescribing Information. Exelixis, Inc. Alameda, CA. September 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 6, 2024.
3. Patel K, Yip L, Lubitz C et al. The American Association of Endocrine Surgeons Guidelines for the Definitive Surgical Management of Thyroid Disease in Adults. Ann Surg. 2020;271(3):e21-e93.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233225
Guideline Name	Cabotegravir Containing Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	3/17/2021
P&T Revision Date:	3/20/2024

1 . Indications

Drug Name: Cabenuva (cabotegravir and rilpivirine) Injection
Treatment of HIV-1 Infection Indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.
Drug Name: Vocabria (cabotegravir) Tablet
Treatment of HIV-1 Infection Indicated in combination with EDURANT (rilpivirine) for short-term treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. Vocabria may be used as: 1) Oral lead-in to assess the tolerability of cabotegravir prior to administration of Cabenuva extended-release injectable suspension for HIV-1 treatment. 2) Oral therapy for patients who will miss

planned injection dosing with Cabenuva for HIV-1 treatment.

HIV-1 Pre-Exposure Prophylaxis Indicated in at-risk adults and adolescents weighing at least 35 kg for short-term pre exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Vocabria may be used as: 1) Oral lead-in to assess the tolerability of cabotegravir prior to administration of Apretude extended-release injectable suspension for HIV-1 PrEP. 2) Oral therapy for patients who will miss planned injection dosing with Apretude for HIV-1 PrEP.

2 . Criteria

Product Name:Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABENUVA	CABOTEGRAVIR 400 MG/2ML & RILPIVIRINE 600 MG/2ML IM SUSP ER	1210990225G120	Brand
CABENUVA	CABOTEGRAVIR 600 MG/3ML & RILPIVIRINE 900 MG/3ML IM SUSP ER	1210990225G130	Brand
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - For continuation of prior therapy

Notes	*If patient meets criteria above, please approve both Vocabria and Ca benuva at GPI list “CABOTEGRPA”.

Product Name:Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

CABENUVA	CABOTEGRAVIR 400 MG/2ML & RILPIVIRINE 600 MG/2ML IM SUSP ER	1210990225G120	Brand
CABENUVA	CABOTEGRAVIR 600 MG/3ML & RILPIVIRINE 900 MG/3ML IM SUSP ER	1210990225G130	Brand
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 70-day gap in therapy [A]

Notes	*If patient meets criteria above, please approve both Vocabria and Cabenuva at GPI list “CABOTEGRPA”.

Product Name:Vocabria**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand

Approval Criteria

1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

AND

2 - Patient's weight is greater than or equal to 35 kg

AND

3 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

4 - One of the following:

4.1 Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg

OR

4.2 Provider attests to both of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens
- Patient would be adherent to testing and dosing schedule

Notes	**If patient meets criteria above, please approve Vocabria at GPI list " APRETUDEPA"

Product Name:Vocabria**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand

Approval Criteria

1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

AND

2 - Patient's weight is greater than or equal to 35 kg

AND

3 - Submission of medical records (e.g., chart notes) confirming documentation of both the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

4.1 Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg

OR

4.2 Both of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens
- Patient would be adherent to testing and dosing schedule

Notes	**If patient meets criteria above, please approve Vocabria at GPI list " APRETUDEPA"

3 . Endnotes

A. Continuation of therapy for Cabenuva and Vocabria in NF criteria will allow for a 70-day gap to account for the 2-month dosing schedule +/- 7 days. [1]

4 . References

1. Cabenuva Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. December 2023.
2. Vocabria Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. December 2023.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228383
Guideline Name	Calquence (acalabrutinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Calquence (acalabrutinib)
Mantle Cell Lymphoma (MCL) Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. **Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)** Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

2 . Criteria

Product Name:Calquence

Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CALQUENCE	ACALABRUTINIB CAP 100 MG	21532103000120	Brand
CALQUENCE	ACALABRUTINIB MALEATE TAB 100 MG	21532103500320	Brand

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Patient has received at least one prior therapy for MCL

Product Name:Calquence	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CALQUENCE	ACALABRUTINIB CAP 100 MG	21532103000120	Brand
CALQUENCE	ACALABRUTINIB MALEATE TAB 100 MG	21532103500320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Calquence

Diagnosis	Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CALQUENCE	ACALABRUTINIB CAP 100 MG	21532103000120	Brand
CALQUENCE	ACALABRUTINIB MALEATE TAB 100 MG	21532103500320	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma

Product Name:Calquence	
Diagnosis	Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CALQUENCE	ACALABRUTINIB CAP 100 MG	21532103000120	Brand
CALQUENCE	ACALABRUTINIB MALEATE TAB 100 MG	21532103500320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Calquence Capsule Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. March 2022.
2. Calquence Tablet Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. August 2022.

Prior Authorization Guideline

Guideline ID	GL-228775
Guideline Name	Camzyos (mavacamten) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Camzyos (mavacamten)
Obstructive hypertrophic cardiomyopathy (HCM) Indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

2 . Criteria

Product Name:Camzyos	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CAMZYOS	MAVACAMTEN CAP 2.5 MG	40190050000110	Brand
CAMZYOS	MAVACAMTEN CAP 5 MG	40190050000120	Brand
CAMZYOS	MAVACAMTEN CAP 10 MG	40190050000130	Brand
CAMZYOS	MAVACAMTEN CAP 15 MG	40190050000140	Brand

Approval Criteria

1 - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)

AND

2 - Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain)

AND

3 - Patient has a left ventricular ejection fraction of greater than or equal to 55%

AND

4 - Patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation

AND

5 - Trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose: [2]

- non-vasodilating beta blocker (e.g., bisoprolol, propranolol)
- calcium channel blocker (e.g., verapamil, diltiazem)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name:Camzyos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CAMZYOS	MAVACAMTEN CAP 2.5 MG	40190050000110	Brand
CAMZYOS	MAVACAMTEN CAP 5 MG	40190050000120	Brand
CAMZYOS	MAVACAMTEN CAP 10 MG	40190050000130	Brand
CAMZYOS	MAVACAMTEN CAP 15 MG	40190050000140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improved symptom relief)

AND

2 - Patient has a left ventricular ejection fraction of greater than or equal to 50% [A, B, 1]

AND

3 - Prescribed by or in consultation with a cardiologist

Product Name:Camzyos	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

CAMZYOS	MAVACAMTEN CAP 2.5 MG	40190050000110	Brand
CAMZYOS	MAVACAMTEN CAP 5 MG	40190050000120	Brand
CAMZYOS	MAVACAMTEN CAP 10 MG	40190050000130	Brand
CAMZYOS	MAVACAMTEN CAP 15 MG	40190050000140	Brand

Approval Criteria

1 - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)

AND

2 - Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain)

AND

3 - Submission of medical records (e.g., chart notes) documenting patient has a left ventricular ejection fraction of greater than or equal to 55%

AND

4 - Submission of medical records (e.g., chart notes) documenting patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose: [2]

- non-vasodilating beta blocker (e.g., bisoprolol, propranolol)
- calcium channel blocker (e.g., verapamil, diltiazem)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name:Camzyos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CAMZYOS	MAVACAMTEN CAP 2.5 MG	40190050000110	Brand
CAMZYOS	MAVACAMTEN CAP 5 MG	40190050000120	Brand
CAMZYOS	MAVACAMTEN CAP 10 MG	40190050000130	Brand
CAMZYOS	MAVACAMTEN CAP 15 MG	40190050000140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improved symptom relief)

AND

2 - Submission of medical records (e.g., chart notes) documenting patient has a left ventricular ejection fraction of greater than or equal to 50% [A, B, 1]

AND

3 - Prescribed by or in consultation with a cardiologist

3 . Endnotes

A. Patients may develop heart failure while taking CAMZYOS. Regular LVEF and Valsalva left ventricular outflow tract (LVOT) gradient assessment is required for careful titration to achieve an appropriate target Valsalva LVOT gradient, while maintaining LVEF ≥50% and avoiding heart failure symptoms. [1]
B. If LVEF <50% while taking Camzyos, interrupt treatment. [1]

4 . References

1. Camzyos prescribing information. MyoKardia, Inc. Brisbane, CA. April 2024.
2. Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy. Circulation. 2020;142(25).

Prior Authorization Guideline

Guideline ID	GL-228812
Guideline Name	Cannabinoids
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Marinol (dronabinol) capsule, Syndros (dronabinol) oral solution
Chemotherapy-induced nausea and vomiting Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. **Anorexia in patients with AIDS** Indicated in adults for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS)

2 . Criteria

Product Name:Brand Marinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MARINOL	DRONABINOL CAP 2.5 MG	50300030000110	Brand
MARINOL	DRONABINOL CAP 5 MG	50300030000115	Brand
MARINOL	DRONABINOL CAP 10 MG	50300030000120	Brand

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Trial and failure, contraindication, or intolerance to formulary generic dronabinol capsules*

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes	*This product may require prior authorization.

Product Name:Generic dronabinol

Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DRONABINOL	DRONABINOL CAP 2.5 MG	50300030000110	Generic
DRONABINOL	DRONABINOL CAP 5 MG	50300030000115	Generic
DRONABINOL	DRONABINOL CAP 10 MG	50300030000120	Generic

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name:Syndros	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNDROS	DRONABINOL SOLN 5 MG/ML	0300030002020	Brand

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - One of the following:

- Trial and failure or intolerance to formulary generic dronabinol capsules*
- Patient is unable to swallow capsules

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes	*This product may require prior authorization.

Product Name:Brand Marinol	
Diagnosis	Anorexia in Patients with AIDS

Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MARINOL	DRONABINOL CAP 2.5 MG	50300030000110	Brand
MARINOL	DRONABINOL CAP 5 MG	50300030000115	Brand
MARINOL	DRONABINOL CAP 10 MG	50300030000120	Brand

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

AND

4 - Trial and failure or intolerance to formulary generic dronabinol capsules*

Notes	*This product may require prior authorization.

Product Name:Generic dronabinol	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DRONABINOL	DRONABINOL CAP 2.5 MG	50300030000110	Generic
DRONABINOL	DRONABINOL CAP 5 MG	50300030000115	Generic
DRONABINOL	DRONABINOL CAP 10 MG	50300030000120	Generic

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

Product Name:Syndros	
Diagnosis	Anorexia in Patients with AIDS

Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNDROS	DRONABINOL SOLN 5 MG/ML	50300030002020	Brand

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-4, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

AND

4 - One of the following:

- Trial and failure or intolerance to formulary generic dronabinol capsules*
- Patient is unable to swallow capsules

Notes	*This product may require prior authorization.

3 . Endnotes

A. Per NCCN, cannabinoids are agents that can be used for breakthrough treatment. Other agents used for breakthrough treatment include: phenothiazines (prochlorperazine, promethazine), prokinetic agents (metoclopramide), antipsychotic agents (haloperidol, olanzapine), corticosteroids (dexamethasone), benzodiazepines (lorazepam), and 5-HT3 receptor antagonists (dolasetron, granisetron, ondansetron). [1]

4 . References

1. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Antiemesis v.1.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed March 9, 2022.
2. Marinol prescribing information. Patheon Softgels, Inc. High Point, NC. March 2021.
3. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed August 22, 2016.
4. American Geriatrics Society 2019 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;00:1-21.
5. Pascual Lopez A, Roque i Figuls M, Urrutia Cuchi G, et al. Systematic review of megestrol acetate in the treatment of anorexia-cachexia syndrome. J Pain Symptom Manage 2004;27:360-369.
6. Per clinical consult with HIV specialist, February 4, 2013.
7. Syndros prescribing information. Benuvia Therapeutics, Inc. Chandler, AZ. January 2021.
8. Williams B, Waters D, Parker K. Evaluation and Treatment of Weight Loss in Adults with HIV Disease. Am Fam Physician. 1999;60(3):843-854.
9. Grinspoon S, Mulligan K; Department of Health and Human Services Working Group on the Prevention and Treatment of Wasting and Weight Loss. Weight loss and wasting in patients infected with human immunodeficiency virus. Clin Infect Dis. 2003;36(Suppl 2):S69-78.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Caprelsa (vandetanib)

Prior Authorization Guideline

Guideline ID	GL-228810
Guideline Name	Caprelsa (vandetanib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Caprelsa (vandetanib)
Medullary Thyroid Cancer (MTC) Indicated for the treatment of symptomatic or progressive MTC in patients with unresectable locally advanced or metastatic disease. Use Caprelsa in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of Caprelsa.

2 . Criteria

Product Name:Caprelsa	
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CAPRELSA	VANDETANIB TAB 100 MG	21533085000320	Brand
CAPRELSA	VANDETANIB TAB 300 MG	21533085000340	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Metastatic medullary thyroid cancer (MTC)
- Unresectable locally advanced MTC

AND

2 - One of the following:

- Patient has symptomatic disease
- Patient has progressive disease

Product Name:Caprelsa	
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CAPRELSA	VANDETANIB TAB 100 MG	21533085000320	Brand
CAPRELSA	VANDETANIB TAB 300 MG	21533085000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Caprelsa prescribing information. Genzyme Corporation. Cambridge, MA. April 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Carbaglu (carglumic acid)

Prior Authorization Guideline

Guideline ID	GL-228778
Guideline Name	Carbaglu (carglumic acid)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Carbaglu (carglumic acid) tablets for oral suspension
Acute Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency Indicated in pediatric and adult patients as adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to NAGS deficiency. **Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency** Indicated in pediatric and adult patients as maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency. **Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)** Indicated in pediatric and adult patients as adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).

2 . Criteria

Product Name:Brand Carbaglu, Generic carglumic acid	
Diagnosis	Acute Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CARGLUMIC ACID	CARGLUMIC ACID SOLUBLE TAB 200 MG	30908230007320	Generic
CARBAGLU	CARGLUMIC ACID SOLUBLE TAB 200 MG	30908230007320	Brand

Approval Criteria

1 - Diagnosis of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency

AND

2 - Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g., protein restriction, ammonia scavengers, dialysis)

AND

3 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name:Brand Carbaglu, Generic carglumic acid	
Diagnosis	Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

CARGLUMIC ACID	CARGLUMIC ACID SOLUBLE TAB 200 MG	30908230007320	Generic
CARBAGLU	CARGLUMIC ACID SOLUBLE TAB 200 MG	30908230007320	Brand

Approval Criteria

1 - Diagnosis of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)

AND

2 - Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g. intravenous glucose, insulin, protein restriction, dialysis)

AND

3 - Patient's plasma ammonia level is greater than or equal to 50 micromol/L

AND

4 - Medication will be used for a maximum duration of 7 days

AND

5 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name:Brand Carbaglu, Generic carglumic acid	
Diagnosis	Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CARGLUMIC ACID	CARGLUMIC ACID SOLUBLE TAB 200 MG	30908230007320	Generic
CARBAGLU	CARGLUMIC ACID SOLUBLE TAB 200 MG	30908230007320	Brand

Approval Criteria

1 - Diagnosis of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency

AND

2 - NAGS deficiency has been confirmed by genetic/mutational analysis

AND

3 - Medication will be used as maintenance therapy

AND

4 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name:Brand Carbaglu, Generic carglumic acid	
Diagnosis	Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CARGLUMIC ACID	CARGLUMIC ACID SOLUBLE TAB 200 MG	30908230007320	Generic

CARBAGLU	CARGLUMIC ACID SOLUBLE TAB 200 MG	30908230007320	Brand

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., plasma ammonia level within the normal range)

3 . References

1. Carbaglu tablet, for suspension. Recordati Rare Diseases Inc , Lebanon, NJ, September 2021.
2. Kenneson, A., Singh, R.H. Presentation and management of N-acetylglutamate synthase deficiency: a review of the literature. Orphanet J Rare Dis 15, 279 (2020).
3. Baumgartner MR, Hörster F, Dionisi-Vici C, et al. Proposed guidelines for the diagnosis and management of methylmalonic and propionic acidemia. Orphanet J Rare Dis. 2014;9:130.

Prior Authorization Guideline

Guideline ID	GL-228815
Guideline Name	Cayston (aztreonam for inhalation solution) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cayston (aztreonam for inhalation solution)
Cystic Fibrosis Indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with Pseudomonas aeruginosa. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV1 less than 25% or greater than 75% predicted, or patients colonized with Burkholderia cepacia. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cayston and other antibacterial drugs, Cayston should be used only to treat patients with CF known to have Pseudomonas aeruginosa in the lungs.

2 . Criteria

Product Name:Cayston	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CAYSTON	AZTREONAM LYSINE FOR INHAL SOLN 75 MG (BASE EQUIVALENT)	16140010402120	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis

AND

2 - Patient has evidence of Pseudomonas aeruginosa in the lungs

AND

3 - Patient is seven years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to TWO of the following:

- Bethkis* (tobramycin [300 mg/4 ml] inhalation solution)
- TOBI* (tobramycin [300 mg/5 ml] inhalation solution)
- Tobi Podhaler (tobramycin capsule)

Notes	*NOTE: Step Therapy (ST) requirements may apply for brand Bethkis and brand TOBI

Product Name:Cayston	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CAYSTON	AZTREONAM LYSINE FOR INHAL SOLN 75 MG (BASE EQUIVALENT)	16140010402120	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis

AND

2 - Patient has evidence of Pseudomonas aeruginosa in the lungs

AND

3 - Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

Product Name:Cayston	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CAYSTON	AZTREONAM LYSINE FOR INHAL SOLN 75 MG (BASE EQUIVALENT)	16140010402120	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of cystic fibrosis

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has evidence of Pseudomonas aeruginosa in the lungs

AND

3 - Patient is seven years of age or older

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:

- generic tobramycin [300 mg/4 ml] inhalation solution
- generic tobramycin [300 mg/5 ml] inhalation solution
- Tobi Podhaler (tobramycin capsule)

3 . References

1. Cayston Prescribing Information. Gilead Sciences, Inc. Foster City, CA. November 2019.
2. Retsch-Bogart GZ, Quittner AL, Gibson RL, et al. Efficacy and safety of inhaled aztreonam lysine for airway Pseudomonas in cystic fibrosis. Chest. 2009;135:1223-32.
3. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic Fibrosis Foundation Pulmonary Guideline. Pharmacologic approaches to prevention and eradication of initial Pseudomonas aeruginosa infection. Ann Am Thorac Soc. 2014;11(10):1640-50.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228385
Guideline Name	Cequa (cyclosporine 0.09%)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cequa (cyclosporine 0.09%) ophthalmic solution
Keratoconjunctivitis sicca Indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

2 . Criteria

Product Name:Cequa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CEQUA	CYCLOSPORINE (OPHTH) SOLN 0.09% (PF)	86720020002040	Brand

Approval Criteria

1 - Diagnosis of keratoconjunctivitis sicca (dry eye)

Product Name:Cequa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CEQUA	CYCLOSPORINE (OPHTH) SOLN 0.09% (PF)	86720020002040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms).

3 . Endnotes

A. As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (i.e., emulsions, gels, and ointments can be used). Anti-inflammatory therapies (topical cyclosporine and corticosteroids), systemic omega-3 fatty acid supplements, punctual plugs and spectacle side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management. [2]

4 . References

1. Cequa Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. March 2021.

2. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern. November 2018. https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018. Accessed January 28, 2022.

Prior Authorization Guideline

Guideline ID	GL-228816
Guideline Name	CGRP Inhibitors - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), Vyepti (eptinezumab-jjmr); Qulipta (atogepant)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.
Drug Name: Emgality (galcanezumab-gnlm)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults. **Episodic Cluster Headache** Indicated for the treatment of episodic cluster headache in adults.
Drug Name: Nurtec ODT (rimegepant)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults.

Preventive Treatment of Episodic Migraine Indicated for the preventive treatment of episodic migraine in adults.
Drug Name: Ubrelvy (ubrogepant), Zavzpret (zavegepant)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Ubrelvy AND Zavzpret are not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name:Aimovig or Ajovy	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AIMOVIG	ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-INJECTOR 70 MG/ML	6770202010D520	Brand
AIMOVIG	ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML	6770202010D540	Brand
AJOVY	FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN PREF SYR 225 MG/1.5ML	6770203020E520	Brand
AJOVY	FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN AUTO-INJ 225 MG/1.5ML	6770203020D520	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has greater than or equal to 4 migraine days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name:Aimovig or Ajovy	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AJOVY	FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN PREF SYR 225 MG/1.5ML	6770203020E520	Brand
AIMOVIG	ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-INJECTOR 70 MG/ML	6770202010D520	Brand
AIMOVIG	ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML	6770202010D540	Brand
AJOVY	FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN AUTO-INJ 225 MG/1.5ML	6770203020D520	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines)

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name:Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN AUTO-INJECTOR 120 MG/ML	6770203530D520	Brand
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 120 MG/ML	6770203530E520	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has greater than or equal to 4 migraine days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Trial and failure, contraindication, or intolerance to BOTH of the following:

- Aimovig
- Ajovy

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Notes	*QL Override for Emgality (For new starts only): For migraine, please enter 2 PAs with the same start date as follows: First PA: Approve two pens or syringes per 30 days for 1 month with a fill count of 2 (Loading dose has a MDD of 0.067); Second PA: Approve one pen or syringe per 30 days (no overrides needed) for 6 months. (Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen/syringe per 30 days)

Product Name:Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN AUTO-INJECTOR 120 MG/ML	6770203530D520	Brand
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 120 MG/ML	6770203530E520	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines)

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

AND

5 - Trial and failure, contraindication, or intolerance to BOTH of the following:

- Aimovig
- Ajovy

Product Name:Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 months [E]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN AUTO-INJECTOR 120 MG/ML	6770203530D520	Brand
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 120 MG/ML	6770203530E520	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.1.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 4 migraine days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic migraines

AND

1.2.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Both of the following:

4.1 Submission of medical records (e.g., chart notes) confirming a history of failure after at least a 12 week trial to BOTH of the following (unless there is a contraindication or intolerance):

- Aimovig
- Ajovy

AND

4.2 Submission of medical records (e.g., chart notes) confirming a history of failure after at least an 8 week trial to ONE of the following (unless there is a contraindication or intolerance):

- Nurtec
- Qulipta

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Notes	*QL Override for Emgality (For new starts only): For migraine, please enter 2 PAs with the same start date as follows: First PA: Approve two pens or syringes per 30 days for 1 month with a fill count of 2 (Loading dose has a MDD of 0.066); Second PA: Approve one pen or syringe per 30 days (no overrides needed) for 6 months. (Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen/syringe per 30 days)

Product Name:Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has greater than or equal to 4 migraine days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a qua lity limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.

Product Name:Nurtec ODT

Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines)

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Notes	Nurtec ODT: For use for preventive treatment of migraine, please ente r a quality limit override of #16 tablets per 30 days (MDD, 0.54) for 12 months.

Product Name:Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Both of the following:

1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 4 migraine days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a qua lity limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.

Product Name:Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QULIPTA	ATOGEPANT TAB 10 MG	67701010000310	Brand
QULIPTA	ATOGEPANT TAB 30 MG	67701010000320	Brand
QULIPTA	ATOGEPANT TAB 60 MG	67701010000330	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has greater than or equal to 4 migraine days per month [28]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name:Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QULIPTA	ATOGEPANT TAB 10 MG	67701010000310	Brand
QULIPTA	ATOGEPANT TAB 30 MG	67701010000320	Brand
QULIPTA	ATOGEPANT TAB 60 MG	67701010000330	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed)

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name:Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
QULIPTA	ATOGEPANT TAB 10 MG	67701010000310	Brand
QULIPTA	ATOGEPANT TAB 30 MG	67701010000320	Brand
QULIPTA	ATOGEPANT TAB 60 MG	67701010000330	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.1.2 Submission of medical records (e.g., chart notes) confirming the patient greater than or equal to 4 migraine days per month [28]

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic migraines

AND

1.2.2 Submission of medical records (e.g., chart notes) confirming a patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Submission of medical records (e.g., chart notes) confirming a medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments to migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name:Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYEPTI	EPTINEZUMAB-JJMR IV SOLN 100 MG/ML	67702015202020	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has greater than or equal to 4 migraine days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventative treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Trial and failure, contraindication or intolerance to BOTH of the following:

- Aimovig

- Ajovy

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name:Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYEPTI	EPTINEZUMAB-JJMR IV SOLN 100 MG/ML	67702015202020	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines)

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

4 - Trial and failure, contraindication, or intolerance to BOTH of the following:

- Aimovig
- Ajovy

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name:Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VYEPTI	EPTINEZUMAB-JJMR IV SOLN 100 MG/ML	67702015202020	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.1.2 Submission of medical records (e.g., chart notes) the patient has greater than or equal to 4 migraine days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic migraines

AND

1.2.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventative treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Both of the following:

4.1 Submission of medical records (e.g., chart notes) confirming a history of failure after at least a 12 week trial to BOTH of the following (unless there is a contraindication or intolerance):

- Aimovig
- Ajovy

AND

4.2 Submission of medical records (e.g., chart notes) confirming a history of failure after at least an 8 week trial to ONE of the following (unless there is a contraindication or intolerance):

- Nurtec ODT
- Qulipta

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name:Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 100 MG/ML	6770203530E515	Brand

Approval Criteria

1 - Diagnosis of episodic cluster headache

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months [21]

AND

3 - Patient is 18 years of age or older [I]

AND

4 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name:Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 100 MG/ML	6770203530E515	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed)

AND

2 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name:Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, one of the following [D, 24]:

5.1 Patient must be currently treated with ONE preventive treatment for migraine from the following:

- Elavil [amitriptyline]
- Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium]
- Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan

- Lisinopril

OR

5.2 Patient has a history of failure (after at least a two month trial), contraindication or intolerance to ONE preventative treatment for migraine from the following:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name:Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name:Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - Paid claims or submission of medical records (e.g., chart notes) one of the following: [D, 24]

5.1 Patient must be currently treated with ONE preventive treatment for migraine from the following:

- Elavil [amitriptyline]
- Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium]
- Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

OR

5.2 Patient has a history of failure (after at least a two month trial), contraindication, or intolerance to THREE preventative treatments for migraine from the following different mechanisms of action:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name:Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UBRELVY	UBROGEPANT TAB 50 MG	67701080000320	Brand
UBRELVY	UBROGEPANT TAB 100 MG	67701080000340	Brand

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, one of the following [D, 24]:

5.1 Patient must be currently treated with ONE preventive treatment for migraine from the following:

- Elavil [amitriptyline]
- Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium]
- Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

OR

5.2 Patient has a history of failure (after at least a two month trial), contraindication or intolerance to ONE preventative treatment for migraine from the following:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name:Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UBRELVY	UBROGEPANT TAB 50 MG	67701080000320	Brand
UBRELVY	UBROGEPANT TAB 100 MG	67701080000340	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Will not be used for preventive treatment of migraine

AND

3 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines

Product Name:Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
UBRELVY	UBROGEPANT TAB 50 MG	67701080000320	Brand
UBRELVY	UBROGEPANT TAB 100 MG	67701080000340	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the ACUTE treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, one of the following: [D, 24]

5.1 Patient must be currently treated with ONE preventive treatment for migraine from the following:

- Elavil [amitriptyline]
- Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium]
- Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

OR

5.2 Patient has a history of failure (after at least a two month trial), contraindication, or intolerance to THREE preventative treatments for migraine from the following:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name:Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZAVZPRET	ZAVEGEPANT HCL NASAL SPRAY 10 MG/ACT	67701090202020	Brand

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, one of the following: [D, 24]

5.1 Patient must be currently treated with ONE preventive treatment for migraine from the following:

- Elavil [amitriptyline]
- Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium]
- Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan

- Lisinopril

OR

5.2 Patient has a history of failure (after at least a two month trial), contraindication, or intolerance to ONE preventative treatment for migraine from the following:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name:Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZAVZPRET	ZAVEGEPANT HCL NASAL SPRAY 10 MG/ACT	67701090202020	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Will not be used for preventive treatment of migraine

AND

3 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

3 . Endnotes

A. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [11]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.
B. While every patient with chronic migraine should receive preventive therapy, not every patient with episodic migraine needs prevention [12]. Appropriate candidates for preventative treatment include those with at least 4 days per month of headache-related disability.
C. The phase 3 inclusion criteria for the erenumab (LIBERTY, STRIVE, ARISE) and galcanezumab (EVOLVE-1, EVOLVE-2) pivotal trials in episodic migraine required that patients had 4 to 14 migraine days per month [3-9]. The LEADER trial evaluated patients who had failed two to four prior preventive migraine treatments (PMTs). At the start of the trial, 38.6%, 37.8%, and 22.8% of patients had failed two, three, and four prior PMTs, respectively [2].
D. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan [16, 24].
E. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [15]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
F. The OptumRx clinical team consulted with a neurologist on the prospective review of the CGPR Inhibitors [14]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more on patient specific factors. Also, he felt that this agent will most likely fall into a similar place in therapy as Botox (onabotulinumtoxin A).
G. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [13].

H. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [11]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
I. The safety and effectiveness in pediatric patients has not been established [1, 17-19, 20, 22, 29].
J. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS). [25]

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Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society. Sept 2019. Available at : https://n.neurology.org/content/93/11/487.long. Accessed July 7, 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228388
Guideline Name	Chenodal (chenodiol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Chenodal (chenodiol)
Radiolucent Gallstones Indicated for patients with radiolucent stones in well-opacifying gallbladders, in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age. The likelihood of successful dissolution is far greater if the stones are floatable or small. For patients with nonfloatable stones, dissolution is less likely and added weight should be given to the risk that more emergent surgery might result from a delay due to unsuccessful treatment. Safety of use beyond 24 months is not established. Chenodiol will not dissolve calcified (radiopaque) or radiolucent bile pigment stones.

2 . Criteria

Product Name:Chenodal

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHENODAL	CHENODIOL TAB 250 MG	52100010000305	Brand

Approval Criteria

1 - Diagnosis of radiolucent gallstones

AND

2 - Patient has a well-opacifying gallbladder visualized by oral cholecystography

AND

3 - Trial and failure, contraindication or intolerance to ursodiol

AND

4 - Patient is not a candidate for surgery

AND

5 - Stones are not calcified (radiopaque) or radiolucent bile pigment stones

AND

6 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- A provider who has specialized expertise in the management of gallstones

Product Name:Chenodal	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHENODAL	CHENODIOL TAB 250 MG	52100010000305	Brand

Approval Criteria

1 - Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment as evidenced by oral cholecystograms or ultrasonograms

AND

2 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- A provider who has specialized expertise in the management of gallstones

3 . References

1. Chenodal Prescribing Information. Travere Therapeutics. San Diego, CA. July 2023.

Prior Authorization Guideline

Guideline ID	GL-228817
Guideline Name	Cholbam (cholic acid)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cholbam (cholic acid)
Bile acid synthesis disorders due to single enzyme defects (SEDs) Indicated for the treatment of bile acid synthesis disorders due to single enzyme defects (SEDs). Limitation of use: The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders have not been established. **Peroxisomal disorders including Zellweger spectrum disorders** Indicated for adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption. Limitation of use: The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders have not been established.

2 . Criteria

Product Name:Cholbam	
Diagnosis	Bile acid synthesis disorders
Approval Length	4 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHOLBAM	CHOLIC ACID CAP 50 MG	52700025000120	Brand
CHOLBAM	CHOLIC ACID CAP 250 MG	52700025000140	Brand

Approval Criteria

1 - Diagnosis of a bile acid synthesis disorder due to a single enzyme defect based on one of the following: [1-6,8,A,B]

- An abnormal urinary bile acid analysis by mass spectrometry
- Molecular genetic testing consistent with the diagnosis

AND

2 - Prescribed by one of the following: [2,7,E]

- Hepatologist
- Medical geneticist
- Pediatric gastroenterologist
- Other specialist that treats inborn errors of metabolism

Product Name:Cholbam	
Diagnosis	Peroxisomal disorders
Approval Length	4 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHOLBAM	CHOLIC ACID CAP 50 MG	52700025000120	Brand
CHOLBAM	CHOLIC ACID CAP 250 MG	52700025000140	Brand

Approval Criteria

1 - Diagnosis of a peroxisomal disorder based on one of the following: [2-5,8,C,D]

- An abnormal urinary bile acid analysis by mass spectrometry
- Molecular genetic testing consistent with the diagnosis

AND

2 - Patient exhibits manifestations of at least one of the following: [2-3]

- Liver disease (e.g., jaundice, elevated serum transaminases)
- Steatorrhea
- Complications from decreased fat-soluble vitamin absorption (e.g., poor growth)

AND

3 - Prescribed by one of the following: [2,7,E]

- Hepatologist
- Medical geneticist
- Pediatric gastroenterologist
- Other specialist that treats inborn errors of metabolism

AND

4 - Used as adjunctive treatment [2-3]

Product Name:Cholbam	
Diagnosis	Bile acid synthesis disorders or Peroxisomal disorders
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHOLBAM	CHOLIC ACID CAP 50 MG	52700025000120	Brand
CHOLBAM	CHOLIC ACID CAP 250 MG	52700025000140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT])

3 . Endnotes

A. Congenital deficiencies in the enzymes responsible for catalyzing key reactions in the synthesis of primary bile acids cholic acid and chenodeoxycholic acid are referred to as bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs). [1] 3 beta-hydroxy-D5-C27-steroid oxidoreductase deficiency (3 beta-HSD) and D4-3-oxosteroid 5 beta-reductase deficiency (AKR1D1 or D4-3-oxo-R), inherited by an autosomal recessive mode, are the most frequent inborn errors of primary bile acid synthesis causing early cirrhosis and liver failure. [6] See Background Table 1 for a list of known bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs). [1]
B. 2- (or alpha-) methylacyl-CoA racemase (AMACR) deficiency is a deficiency of a single peroxisomal enzyme that may manifest secondary abnormalities of bile acid synthesis; it may thus technically be considered a BASD, as well as, a peroxisomal disorder (PD). [2-5]
C. The spectrum of diseases referred to as peroxisomal disorders (PDs) involve defects in later steps of the bile acid synthetic pathway, such as impaired side-chain oxidation; [3] PDs are therefore classified as either disorders of peroxisome biogenesis (eg, Zellweger syndrome) or deficiencies of a single peroxisomal enzyme (eg, 2- (or alpha-)methylacyl-CoA racemase [AMACR] deficiency). [3] See Background Table 2 for a list of known PDs. [5]
D. Zellweger syndrome, infantile Refsum disease, neonatal adrenoleukodystrophy and rhizomelic chondrodysplasia punctata type 1 (RCDP1) are examples of defective biogenesis in which peroxisomes are absent. [4-5] The first 3 disorders are thought to represent a clinical continuum, referred to as Zellweger spectrum disorders (ZSD), with Zellweger syndrome the most severe, infantile Refsum disease the mildest, and neonatal adrenoleukodystrophy intermediate in severity. [5]
E. As per the prescribing information [2], treatment with Cholbam should be initiated and monitored by an experienced hepatologist or pediatric gastroenterologist. At the University of California, San Francisco, medical geneticists see patients with PDs, while specialists in pediatric gastroenterology see patients with BASDs. [7]

F. Cholbam should be discontinued if liver function does not improve within 3 months of starting treatment. [2] An additional month is added to the initial authorization duration to allow for patient follow-up with the provider.

4 . References

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5. Wanders RJA. Peroxisomal disorders. UpToDate web site. https://www.uptodate.com/contents/peroxisomal-disorders?search=cholic%20acid&source=search_result&selectedTitle=2%7E9&usage_type=default&display_rank=1. Updated October 13, 2023. Accessed March 4, 2024.
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7. Per email with medical geneticist, June 10, 2015.
8. National Organization for Rare Disorders (NORD). Bile acid sythesis disorders. Available at: https://rarediseases.org/rare-diseases/bile-acid-synthesis-disorders/. Accessed February 9, 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233229
Guideline Name	Cimzia (certolizumab pegol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	5/20/2008
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Cimzia (certolizumab pegol)
Rheumatoid Arthritis (RA) Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis (PsA). **Plaque Psoriasis (PsO)** Indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adults with active ankylosing spondylitis.

Non-radiographic Axial Spondyloarthritis (nr-axSpA) Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

Crohn's Disease (CD) Indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

2 . Criteria

Product Name:Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	5250502010F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	5250502010F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

Product Name:Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	52505020 10F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Cimzia	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	52505020 10F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

Product Name:Cimzia	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	52505020 10F840	Brand

CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Cimzia	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	52505020 10F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [5]:

- actively inflamed joints

- dactylitis
- enthesitis
- axial disease
- active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name:Cimzia	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	52505020106420	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020106420	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name:Cimzia

Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	52505020 10F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis (PsO)

AND

2 - One of the following [6]:

- Greater than or equal to 3% body surface area involvment
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [7]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Cimzia	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	52505020 10F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1, 6]:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Cimzia	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	52505020 10F840	Brand

CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis (AS)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [8]

Product Name:Cimzia	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	52505020 10F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 8]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name:Cimzia	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	5250502010F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	5250502010F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA)

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 8]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [8]

Product Name:Cimzia	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	52505020 10F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 8]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Function
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name:Cimzia	
Diagnosis	Crohn’s disease (CD)
Approval Length	16 Weeks [A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	5250502010F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	5250502010F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - One of the following [9, 10]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [9, 10]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Cimzia	
Diagnosis	Crohn’s disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMZIA	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML	5250502010F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	5250502010F840	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 9, 10]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

3 . Endnotes

A. The recommended initial adult dose of Cimzia is 400 mg (given as two subcutaneous injections of 200 mg) initially, and at Weeks 2 and 4. In patients who obtain a clinical response, the recommended maintenance regimen is 400 mg every four weeks.

4 . References

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6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
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5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228780
Guideline Name	Cinqair (reslizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cinqair (reslizumab)
Severe Eosinophilic Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype. Limitation of Use: Cinqair is not indicated for treatment of other eosinophilic conditions; Cinqair is not indicated for the relief of acute bronchospasm or status asthmaticus.

2 . Criteria

Product Name:Cinqair	
Approval Length	6 Months [H]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CINQAIR	RESLIZUMAB IV INFUSION SOLN 100 MG/10ML (10 MG/ML)	44604460002020	Brand

Approval Criteria

1 - Diagnosis of severe asthma [1]

AND

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [1, B, D]

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [A]

OR

3.2 Prior asthma-related hospitalization within the past 12 months [D]

AND

5 - Age greater than or equal to 18 years

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1 Both of the following [C, E, F]:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg])

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/immunologist

Product Name:Cinqair	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CINQAIR	RESLIZUMAB IV INFUSION SOLN 100 MG/10ML (10 MG/ML)	44604460002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [6]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320

Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. In two duplicate 52-week Phase III studies, eligible patients were required to have experienced at least one asthma exacerbation that required a systemic corticosteroid for at least 3 days within the past 12 months. [2, 3]
B. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [8]
C. The ERS/ATS guidelines define severe asthma as that which requires treatment with high-dose ICSs plus a second controller (or systemic corticosteroids [CSs]) to prevent progression to uncontrolled disease status or continuing uncontrolled disease status despite this therapy. [4]
D. Recommended per national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.

E. In the pivotal study for Nucala (mepolizumab), another IL-5 antagonist indicated for severe eosinophilic asthma, patients met the inclusion criteria with a well-documented requirement for regular treatment with high dose ICS (i.e., greater than or equal to 880 mcg/day fluticasone propionate or equivalent daily), with or without maintenance oral corticosteroids, in the 12 months prior to Visit 1. [5]
F. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [6]
G. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [6].
H. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [6]

5 . References

1. Cinqair Prescribing Information. Teva Respiratory, LLC. Frazer, PA. June 2020.
2. Castro M, Zangrilli J, Wechsler ME, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts: results from two multicentre, parallel, doubleblind, randomised, placebo-controlled, phase 3 trials. Lancet Respir Med. 2015;3(5):355-366.
3. Bjermer L, Lemiere C, Maspero J, et al. A randomized phase 3 study of the efficacy and safety of reslizumab in subjects with asthma with elevated eosinophils. Eur Respir J. 2014;44(Suppl 58):P299. Paper presented at: European Respiratory Society International Congress; September 6-10, 2014; Munich, Germany.
4. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014; 43:343-373.
5. Pavord ID, Korn S, Howarth P, et al. Mepolizumab for severe eosinophilic asthma (DREAM): a multicentre, double-blind, placebo-controlled trial. Lancet. 2012; 380: 651-59.
6. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed 9 April, 2024.
7. Per clinical consult with allergist specialist. May 4, 2016.
8. Institute for Clinical and Economic Review (ICER). Biologic therapies for treatment of asthma associated with type 2 inflammation: effectiveness, value, and value-based price benchmarks. https://icer.org/wp-content/uploads/2020/10/ICER_Asthma-Final-Report_Unredacted_08122020.pdf. Published December 20, 2018. Accessed 9 April, 2024.

Prior Authorization Guideline

Guideline ID	GL-228390
Guideline Name	Ciprofloxacin-Containing Otic Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cetraxal (ciprofloxacin otic solution)
Acute Otitis Externa Indicated for the treatment of acute otitis externa due to susceptible isolates of Pseudomonas aeruginosa or Staphylococcus aureus.
Drug Name: Ciprodex (ciprofloxacin and dexamethasone otic suspension)
Acute Otitis Media Indicated in pediatric patients (age 6 months and older) with tympanostomy tubes for the treatment of infections caused by susceptible isolates of Staphylococcus aureus, Streptococcus, pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, and Pseudomonas aeruginosa. **Acute Otitis Externa** Indicated in pediatric (age 6 months and older), adult and elderly patients for the treatment of infections caused by susceptible isolates of Staphylococcus aureus and Pseudomonas aeruginosa.

2 . Criteria

Product Name:Brand Cetraxal	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
CETRAXAL	CIPROFLOXACIN HCL OTIC SOLN 0.2% (BASE EQUIVALENT)	87100012102020	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 10-day supply) within the past 180 days, contraindication, or intolerance to generic ofloxacin otic solution

Product Name:Brand Ciprodex	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
CIPRODEX	CIPROFLOXACIN-DEXAMETHASONE OTIC SUSP 0.3-0.1%	87991002361820	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 10-day supply) within the past 180 days, contraindication, or intolerance to generic ofloxacin otic solution

AND

3 - Trial and failure (of a minimum 7-day supply) within the past 180 days, or intolerance to generic ciprofloxacin-dexamethasone otic suspension

3 . References

1. Jones RN, Milazzo J, Seidlin M. Ofloxacin otic solution for treatment of otitis externa in children and adults. Arch Otolaryngol Head Neck Surg 1997;123:1193-200.
2. Cetraxal Prescribing Information. The RiteDose Corporation. Columbia, SC. December 2017.
3. Rosenfeld RM, Schwartz SR, Cannon CR, et al. Clinical practice guideline: acute otitis externa. Otolaryngol Head Neck Surg. 2014;150(1):S1-S24.
4. Ciprodex Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. November 2020.

Prior Authorization Guideline

Guideline ID	GL-233371
Guideline Name	Clinical Duplicates Program
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	10/21/2021
P&T Revision Date:	2/20/2025

Note:

The purpose of this guideline is to establish policies and procedures on how to handle drugs included on the clinical duplicates list. This guideline will not apply to Non-Formulary reviews, drugs that are benefit exclusions, drugs with step therapy edits, drugs that require quantity limit review only, or drugs that are not reviewed for prior authorization by OptumRx.

1 . Criteria

Product Name:Drugs included on the Clinical Duplicates list for which a Drug-Specific Prior Authorization Guideline is Unavailable*	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Clinical			
Duplicates			

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

AND

1.1.3 Requested drug will be used at a dose which is within FDA recommendations

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - One of the following**:

2.1 If the requested drug has a formulary alternative with the same active ingredient, both of the following:

2.1.1 Patient has experienced intolerance (e.g., allergy to excipient) with a formulary alternative that has the same active ingredient

AND

2.1.2 Patient has tried and failed at least 2 additional formulary alternatives within the same therapeutic class. If only 1 formulary alternative within the therapeutic class is available, the patient must have tried the formulary alternative within the therapeutic class AND 1 additional formulary alternative. If there are no formulary alternatives within the same therapeutic class, the patient must have failed 2 formulary alternatives or have a contraindication or intolerance to all formulary alternatives

OR

2.2 If the requested drug is a fixed-dose combination product with each individual ingredients available on formulary, both of the following:

2.2.1 Patient has experienced intolerance (e.g., allergy to excipient) with the individual ingredients in the combination product

AND

2.2.2 Patient has tried and failed at least 2 additional formulary alternatives

OR

2.3 If only over-the-counter (OTC) equivalents^ are available, patient has tried and failed or has contraindications or intolerance to 3 OTC equivalents. If only 1 or only 2 equivalents are available, the patient must have failed or has contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial]

OR

2.4 If formulary alternatives are available and do not meet above scenarios, patient has tried and failed at least 3 formulary alternatives or has contraindications or intolerance to all formulary alternatives. If only 1 or only 2 alternatives are available, the patient must have failed or has contraindications or intolerance to all available formulary alternatives

OR

2.5 No formulary alternative or OTC equivalent^ is available to treat the patient's condition

AND

3 - Submission of medical records (e.g., chart notes) confirming why the requested drug is expected to provide benefit when the formulary alternative(s) or OTC equivalent(s) has not shown to be effective

Notes	*Drug should be reviewed using the drug-specific Prior Authorization guideline if available. If no drug-specific Prior Authorization guideline is available, proceed with the criteria above. ^OTC equivalents refers to any covered or non-covered OTC equivalent product. **Please consult client-specific resources to determine appropriate generic formulary drugs.

Product Name:Abilify Mycite, Brand Levetiracetam, Spritam	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPRITAM	LEVETIRACETAM TAB DISINTEGRATING SOLUBLE 250 MG	7260004300G820	Brand
SPRITAM	LEVETIRACETAM TAB DISINTEGRATING SOLUBLE 500 MG	7260004300G830	Brand
SPRITAM	LEVETIRACETAM TAB DISINTEGRATING SOLUBLE 750 MG	7260004300G840	Brand
SPRITAM	LEVETIRACETAM TAB DISINTEGRATING SOLUBLE 1000 MG	7260004300G850	Brand
ABILIFY MYCITE STARTER KIT	ARIPIPRAZOLE TAB 2 MG WITH SENSOR, STRIPS & POD STARTER PAK	5925001503B705	Brand
ABILIFY MYCITE MAINTENANCE KIT	ARIPIPRAZOLE TAB 2 MG WITH SENSOR&STRIPS (FOR POD) MAINT PAK	5925001503B706	Brand
ABILIFY MYCITE STARTER KIT	ARIPIPRAZOLE TAB 5 MG WITH SENSOR, STRIPS & POD STARTER PAK	5925001503B710	Brand
ABILIFY MYCITE MAINTENANCE KIT	ARIPIPRAZOLE TAB 5 MG WITH SENSOR&STRIPS (FOR POD) MAINT PAK	5925001503B711	Brand
ABILIFY MYCITE STARTER KIT	ARIPIPRAZOLE TAB 10 MG WITH SENSOR, STRIPS & POD STARTER PAK	5925001503B720	Brand
ABILIFY MYCITE MAINTENANCE KIT	ARIPIPRAZOLE TAB 10 MG WITH SENSOR&STRIPS(FOR POD) MAINT PAK	5925001503B721	Brand

ABILIFY MYCITE STARTER KIT	ARIPIPRAZOLE TAB 15 MG WITH SENSOR, STRIPS & POD STARTER PAK	5925001503B730	Brand
ABILIFY MYCITE MAINTENANCE KIT	ARIPIPRAZOLE TAB 15 MG WITH SENSOR&STRIPS(FOR POD) MAINT PAK	5925001503B731	Brand
ABILIFY MYCITE STARTER KIT	ARIPIPRAZOLE TAB 20 MG WITH SENSOR, STRIPS & POD STARTER PAK	5925001503B740	Brand
ABILIFY MYCITE MAINTENANCE KIT	ARIPIPRAZOLE TAB 20 MG WITH SENSOR&STRIPS(FOR POD) MAINT PAK	5925001503B741	Brand
ABILIFY MYCITE STARTER KIT	ARIPIPRAZOLE TAB 30 MG WITH SENSOR, STRIPS & POD STARTER PAK	5925001503B750	Brand
ABILIFY MYCITE MAINTENANCE KIT	ARIPIPRAZOLE TAB 30 MG WITH SENSOR&STRIPS(FOR POD) MAINT PAK	5925001503B751	Brand
Clinical			
Duplicates			
LEVETIRACETAM	LEVETIRACETAM TAB DISINTEGRATING SOLUBLE 250 MG	7260004300G820	Generic

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 All of the following:

1.1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

AND

1.1.1.3 Requested drug will be used at a dose which is within FDA recommendations

OR

1.1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

1.2 One of the following*:

1.2.1 If the requested drug has a formulary alternative with the same active ingredient, both of the following:

1.2.1.1 Patient has experienced intolerance (e.g., allergy to excipient) with a formulary alternative that has the same active ingredient

AND

1.2.1.2 Patient has tried and failed at least 2 additional formulary alternatives within the same therapeutic class. If only 1 formulary alternative within the therapeutic class is available, the patient must have tried the formulary alternative within the therapeutic class AND 1 additional formulary alternative. If there are no formulary alternatives within the same therapeutic class, the patient must have failed 2 formulary alternatives or have a contraindication or intolerance to all formulary alternatives

OR

1.2.2 If the requested drug is a fixed-dose combination product with each individual ingredients available on formulary, both of the following:

1.2.2.1 Patient has experienced intolerance (e.g., allergy to excipient) with the individual ingredients in the combination product

AND

1.2.2.2 Patient has tried and failed at least 2 additional formulary alternatives

OR **1.2.3** If formulary alternatives are available and do not meet above scenarios, patient has tried and failed at least 3 formulary alternatives or has contraindications or intolerance to all formulary alternatives. If only 1 or only 2 alternatives are available, the patient must have failed or has contraindications or intolerance to all available formulary alternatives **OR** **1.2.4** No formulary alternative is available to treat the patient's condition **OR** **1.2.5** For continuation of prior therapy	
Notes	*Please consult client-specific resources to determine appropriate generic formulary drugs.

2 . Revision History

Date	Notes
3/6/2025	Quartz Comm/EHB copied to mirrow to OptumRx

Prior Authorization Guideline

Guideline ID	GL-233294
Guideline Name	Cobenfy (xanomeline and trospium chloride)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/21/2024
P&T Revision Date:	

1 . Indications

Drug Name: Cobenfy (xanomeline and trospium chloride)
Schizophrenia Indicated for the treatment of adults with schizophrenia.

2 . Criteria

Product Name:Cobenfy	
Approval Length	12 Months [A,2]
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
COBENFY STARTER PACK	XANOMELINE-TROSPIUM CHLORIDE CAP PACK 50-20 MG & 100-20 MG	5919990280B220	Brand
COBENFY	XANOMELINE TARTRATE-TROSPIUM CHLORIDE CAP 50-20 MG	59199902800120	Brand
COBENFY	XANOMELINE TARTRATE-TROSPIUM CHLORIDE CAP 100-20 MG	59199902800130	Brand
COBENFY	XANOMELINE TARTRATE-TROSPIUM CHLORIDE CAP 125-30 MG	59199902800135	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following [B,C,1-3]:

- aripiprazole
- asenapine
- clozapine
- olanzapine
- paliperidone
- quetiapine IR/ER
- risperidone
- ziprasidone

OR

2 - For continuation of prior therapy [A,D,2]

3 . Endnotes

A. There is insufficient evidence to recommend for or against any specific duration for treatment with an antipsychotic after response or remission of psychosis [2].
B. Antipsychotics are recommended in acute episodes of schizophrenia or first-episode psychosis who have previously responded to antipsychotics. Medication choice is individualized to patient characteristics and medication side effect profiles [2].
C. Patients experiencing an acute exacerbation or relapse of psychotic symptoms with diagnosed schizophrenia could be eligible for inclusion in the pivotal EMERGENT-3 phase 3 trial if they had previously tried other agents, including oral antipsychotics and lithium therapy [1,3].
D. The continued use of an antipsychotic medication for maintenance treatment of schizophrenia to prevent relapse and hospitalization is recommended in patients who have responded to treatment [2].

4 . References

1. Cobenfy Prescribing Information. Bristol-Myers Squibb. Princeton, NJ. September 2024.
2. Department of Veterans Affairs (VA)/Department of Defense (DoD) Clinical Practice Guideline for Management of First-Episode Psychosis and Schizophrenia. Version 1.0 – 2023. Available at: https://www.healthquality.va.gov/guidelines/MH/scz/VADoDCPGSchizophreniaCPG_Final_508.pdf. Accessed October 10, 2024.
3. Kaul I, Sawchak S, Walling DP, et al. Efficacy and safety of xanomeline-trospium chloride in schizophrenia. JAMA Psychiatry. 2024;81(8):749-56.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228820
Guideline Name	Colony-Stimulating Factors (CSFs) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Fulphila (pegfilgrastim-jmdb, G-CSF), Fylnetra (pegfilgrastim-pbbk), Nyvepria (pegfilgrastim-apgf, G-CSF), Stimufend (pegfilgrastim-fpgk), Ziextenzo (pegfilgrastim-bmez, G-CSF)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Pegfilgrastim is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. **Off Label Uses: Hematopoietic Subsyndrome of Acute Radiation Syndrome** To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M] **Treatment of High-Risk Febrile Neutropenia (FN)** For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]
Drug Name: Granix (tbo-filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to reduce the duration of severe neutropenia in adult and pediatric patients 1 month and older with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [16]

Drug Name: Leukine (sargramostim, GM-CSF)

Acute Myeloid Leukemia (AML) Following Induction Chemotherapy Indicated to shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML).

Autologous Peripheral Blood Progenitor Cell Mobilization and Collection Indicated in adult patients with cancer undergoing autologous hematopoietic stem cell transplantation for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis.

Autologous Peripheral Blood Progenitor Cell and Bone Marrow Transplantation Indicated for the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric patients 2 years of age and older with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's lymphoma (HL).

Allogeneic Bone Marrow Transplantation (BMT) Indicated for the acceleration of myeloid reconstitution in adult and pediatric patients 2 years of age and older undergoing allogeneic bone marrow transplantation from HLA-matched related donors.

Allogeneic or Autologous Bone Marrow Transplantation: Treatment of Delayed Neutrophil Recovery or Graft Failure Indicated for the treatment of adult and pediatric patients 2 years and older who have undergone allogeneic or autologous bone marrow transplantation in whom neutrophil recovery is delayed or failed.

Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS) Indicated to increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

Off Label Uses: Febrile Neutropenia (FN), Prophylaxis Has been used in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever [11]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-

related neutropenia [37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neulasta, Neulasta Onpro (pegfilgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Hematopoietic Subsyndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neupogen (filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation (BMT) Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Autologous Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Hematopoietic Syndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: **Human Immunodeficiency Virus (HIV)-Related Neutropenia** Has been prescribed for HIV-related neutropenia. [11-15, 37]

Hepatitis-C Interferon Induced Neutropenia Neupogen has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Nivestym (filgrastim-aafi, G-CSF), Zarxio (filgrastim-sndz, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Off Label Uses: **Hematopoietic Subsyndrome of Acute Radiation Syndrome** Has been used to increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M]

Hepatitis-C Interferon Induced Neutropenia Has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24, M]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11, 37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Releuko (filgrastim-ayow)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. **Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy** Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML. **Patients with Cancer Undergoing Bone Marrow Transplantation** Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation. **Patients with Severe Chronic Neutropenia (SCN)** Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. **Off Label Uses: Patients Undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy** Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. **Hematopoietic Subsyndrome of Acute Radiation Syndrome** Has been used to increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M] **Hepatitis-C Interferon Induced Neutropenia** Has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24, M] **Human Immunodeficiency Virus (HIV)-Related Neutropenia** Has been prescribed for HIV-related neutropenia. [11, 37] **Treatment of High-Risk Febrile Neutropenia (FN)** Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]
Drug Name: Rolvedon (eflapegrastim-xnst)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Rolvedon is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
Drug Name: Udenyca (pegfilgrastim-cbqv, G-CSF)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving

myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Udenyca is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]

2 . Criteria

Product Name:Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	

RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	

Approval Criteria

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Patient is 2 years of age or older (applies to Leukine only)

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name:Neupogen	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand

Approval Criteria

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name:Leukine	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Patient is 55 years of age or older [3, B]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name:Neupogen	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name:Fulphila, Fylnetra, Granix, Leukine (Off-Label), Neulasta/Neulasta Onpro*, Releuko, Neupogen, Nivestym, Nyvepria, Stimufend, Udenyca/Udenyca Onbody*, Zarxio, or Ziextenzo	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand

ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEULASTA	PEGFILGRASTIM SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157000E520	Brand
NEULASTA ONPRO KIT	PEGFILGRASTIM SOLN PREFILLED SYRINGE KIT 6 MG/0.6ML	8240157000F820	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157010E520	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
STIMUFEND	PEGFILGRASTIM-FPGK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157015E520	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN AUTO-INJECTOR 6 MG/0.6ML	8240157010D520	Brand
ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	Brand
UDENYCA ONBODY	PEGFILGRASTIM-CBQV SOLN PREFILL SYR/INFUSION DEV 6 MG/0.6ML	8240157010E525	Brand

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Notes	*If patient meets criteria above, please approve both Neulasta/Neulasta Onpro, Udenyca/Udenyca Onbody at GPI list “FILGRASTPA”.

Product Name:Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Ziextenzo	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen and Granix only):

- Nivestym
- Zarxio

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name:Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ROLVEDON	EFLAPEGRASTIM-XNST SOLN PREFILLED SYRINGE 13.2 MG/0.6ML	8240151880E520	Brand

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure or intolerance to ONE of the following:

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name:Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ROLVEDON	EFLAPEGRASTIM-XNST SOLN PREFILLED SYRINGE 13.2 MG/0.6ML	8240151880E520	Brand

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following:

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name:Fulphila, Fylnetra, Granix, Leukine, Neulasta/Neulasta Onpro*, Neupogen, Nivestym, Nyvepria, Releuko, Stimufend, Udenyca/Udenyca Onbody*, Zarxio, or Ziextenzo	
Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	3 Months or duration of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEULASTA	PEGFILGRASTIM SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157000E520	Brand
NEULASTA ONPRO KIT	PEGFILGRASTIM SOLN PREFILLED SYRINGE KIT 6 MG/0.6ML	8240157000F820	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand

NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand
STIMUFEND	PEGFILGRASTIM-FPGK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157015E520	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157010E520	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN AUTO-INJECTOR 6 MG/0.6ML	8240157010D520	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	Brand
UDENYCA ONBODY	PEGFILGRASTIM-CBQV SOLN PREFILL SYR/INFUSION DEV 6 MG/0.6ML	8240157010E525	Brand

Approval Criteria

1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, l]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patient is at high risk for infection-associated complications [16, 17, 34]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

AND

5 - One of the following:

5.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

5.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Notes	*If patient meets criteria above, please approve both Neulasta/Neulasta Onpro, Udenyca/Udenyca Onbody at GPI list “FILGRASTPA”.

Product Name:Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Ziextenzo	
Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	3 Months or duration of therapy
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand

GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand

Approval Criteria

1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, l]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patient is at high risk for infection-associated complications [16, 17, 34]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen and Granix only):

- Nivestym
- Zarxio

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name:Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand

NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	

Approval Criteria

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3) [16]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name:Neupogen	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand

Approval Criteria

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3) [16]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name:Fulphila (Off-Label), Fylnetra (Off-label), Granix (Off-Label), Leukine, Neulasta, Neupogen, Nivestym (Off-Label), Nyvepria (Off-Label), Releuko (Off-Label), Stimufend (Off-label), Udenyca, Zarxio (Off-Label), or Ziextenzo (Off-Label)	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	1 Months [N]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEULASTA	PEGFILGRASTIM SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157000E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157010E520	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
STIMUFEND	PEGFILGRASTIM-FPGK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157015E520	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN AUTO-INJECTOR 6 MG/0.6ML	8240157010D520	Brand
ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	Brand

RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	Brand

Approval Criteria

1 - Patient was/will be acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Granix and Releuko only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Stimufend, Ziextenzo only):

- Neulasta
- Udenyca

Product Name:Fulphila (Off-Label), Fylnetra (Off-Label), Granix (Off-Label), Neupogen, Nyvepria (Off-Label), Ziextenzo	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	1 Months [N]

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand

Approval Criteria

1 - Patient was/will be acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen only):

- Nivestym
- Zarxio

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta
- Udenyca

Product Name:Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Human Immunodeficiency Virus (HIV)-Related Neutropenia (Off-Label)
Approval Length	6 months [11, 15, H]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand

RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	

Approval Criteria

1 - Patient is infected with HIV virus [11- 13]

AND

2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name:Neupogen	
Diagnosis	Human Immunodeficiency Virus (HIV)-Related Neutropenia (Off-Label)
Approval Length	6 months [11, 15, H]

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand

Approval Criteria

1 - Patient is infected with HIV virus [11- 13]

AND

2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name:Neupogen, Nivestym, Releuko, Zarxio	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-Label)

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	Brand

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient is infected with Hepatitis C virus

AND

1.1.2 Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.1.3 Patient has neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells/mm3) after dose reduction of Peg-Intron or Pegasys [F]

OR

1.2 Both of the following:

1.2.1 Patient is experiencing interferon-induced neutropenia (ANC less than or equal to 500 cells/mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 One of the following: [G]

1.2.2.1 Patient with Human Immunodeficiency Virus (HIV) co-infection

OR

1.2.2.2 Status post liver transplant

OR

1.2.2.3 Patient with established cirrhosis

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist

- Hepatologist
- Gastroenterologist

AND

3 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name:Neupogen	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-Label)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient is infected with Hepatitis C virus

AND

1.1.2 Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.1.3 Patient has neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells/mm3) after dose reduction of Peg-Intron or Pegasys [F]

OR

1.2 Both of the following:

1.2.1 Patient is experiencing interferon-induced neutropenia (ANC less than or equal to 500 cells/mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 One of the following: [G]

1.2.2.1 Patient with Human Immunodeficiency Virus (HIV) co-infection

OR

1.2.2.2 Status post liver transplant

OR

1.2.2.3 Patient with established cirrhosis

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist
- Hepatologist
- Gastroenterologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

3 . Background

Benefit/Coverage/Program Information

Table 1. Intergroup C9741 Protocol [19]

Regimen	Drugs	G-CSF
Sequential	Doxorubicin q2 weeks x4 cycles, then paclitaxel q2 weeks x4 cycles, then cyclophosphamide q2 weeks x 4cycles	Days 3 to 10 of each cycle
Concurrent	Doxorubicin + cyclophosphamide q2 weeks x4 cycles, then paclitaxel q2 weeks x4 cycles	Days 3 to 10 of each cycle

Table 2. Examples of chemotherapy regimens with a high risk of FN (> 20%) [16]

Cancer	Regimen
Bladder Cancer	• Dose-dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
Bone Cancer	• VAI (vincristine, doxorubicin or dactinomycin, ifosfamide) • VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide) • Cisplatin/doxorubicin • VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin) • VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)
Breast Cancer[18]	• Dose-dense AC followed by dose-dense paclitaxel (doxorubicin, cyclophosphamide, paclitaxel) • TAX (docetaxel, doxorubicin, cyclophosphamide) • TC (docetaxel, cyclophosphamide) • TCH (docetaxel, carboplatin, trastuzumab)
Colorectal Cancer	• FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, irinotecan)
Head and Neck Squamous Cell Carcinoma	• TPF (docetaxel, cisplatin, 5-fluorouracil)
Hodgkin Lymphoma	• Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine) • Escalated BEACOPP (bleomycin, etoposide, doxorubivin, cyclophosphamide, vincristine, procarbazine, prednisone)
Kidney Cancer	• Doxorubicin/gemcitabine
Non-Hodgkin's Lymphomas	• Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) • ICE (ifosfamide, carboplatin, etoposide) • Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) • MINE (mesna, ifosfamide, mitoxantrone, etoposide) • DHAP (dexamethasone, cisplatin, cytarabine) • ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) • HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone)
Melanoma	• Dacarbazine-based combination with IL-2, interferon alfa (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)

Multiple Myeloma	• DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide) +/- bortezomib (VTD-PACE)
Ovarian Cancer	• Topotecan • Docetaxel
Pancreatic Cancer	• FOLFIRINOX (fluorouracil, leucovorin, irinotecan, oxaliplatin)
Soft Tissue Sarcoma	• MAID (mesna, doxorubicin, ifosfamide, dacarbazine) • Doxorubicin • Ifosfamide/doxorubicin
Small Cell Lung Cancer	• Topotecan
Testicular Cancer	• VIP (etoposide, ifosfamide, cisplatin) • VeIP (vinblastine, ifosfamide, cisplatin) • TIP (paclitaxel, ifosfamide, cisplatin)

Table 3. Examples of chemotherapy regimens with an intermediate risk of FN (10-20%) [16]

Cancer	**Regimen**
Occult Primary-Adenocarcinoma	• Gemcitabine/docetaxel
Breast Cancer	• Docetaxel • AC (doxorubicin, cyclophosphamide) + sequential docetaxel (adjuvant) (taxane portion only) • Paclitaxel every 21 days•
Cervical Cancer	• Cisplatin/topotecan • Paclitaxel/cisplatin • Topotecan • Irinotecan
Colorectal Cancer	• FOLFOX (fluorouracil, leucovorin, oxaliplatin)
Non-Hodgkin's Lymphomas (NHL)[26]	• GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) • CHOP (cyclophosphamide, doxorubivin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin • CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin

	• Bendamustine
Non-Small Cell Lung Cancer	• Cisplatin/paclitaxel • Cisplatin/vinorelbine • Cisplatin/docetaxel • Cisplatin/etoposide • Carboplatin/paclitaxel • Docetaxel
Ovarian Cancer	• Carboplatin/docetaxel
Prostate Cancer	• Cabazitaxel
Testicular Cancer	• Etoposide/cisplatin • BEP (bleomycin, etoposide, cisplatin)
Esophageal and Gastric Cancer	• Irinotecan/cisplatin • Epirubicin/cisplatin/5-flurouracil • Epirubicin/cisplatin/capecitabine
Small Cell Lung Cancer	• Etoposide/carboplatin
Uterine Cancer	• Docetaxel

Table 4. Examples of FDA-approved chemotherapeutic agents with dose-limiting myelosuppression

Generic Name	**Brand Name**
Busulfan	Busulfex®, Myleran®
Carboplatin	Paraplatin®
Carmustine (BCNU)	BiCNU®, Gliadel®
Chlorambucil	Leukeran®
Cladribine	Luestatin®
Cyclophosphamide	Cytoxan®
Cytarabine	N/A
Dacarbazine (DTIC)	DTIC-Dome®
Dactinomycin	Actinomycin D®, Cosmegen®
Daunorubicin	Cerubidine®
Daunorubicin Liposomal	DaunoXome®
Doxorubicin	Adriamycin PFS®, Adriamycin RDF®, Adriamycin®
Doxorubicin Liposomal	Doxil®
Etoposide	Etopophos®, Toposar®, VePesid®
Fluorouracil (5-FU)	Adrucil®, Efudex®, Fluoroplex®
Floxuridine	FUDR®
Fludarabine	Fludara®
Hydroxyurea	Droxia®, Hydrea®
Ifosfamide/Mesna	Ifex®, Mesnex®

Lomustine (CCNU)	CeeNU®
Mechlorethamine (Nitrogen Mustard)	Mustargen®
Melphalan	Alkeran®
Mercaptopurine (6-MP)	Purinethol®
Methotrexate	Rheumatrex®, Trexall®
Mitomycin	N/A
Mitoxantrone	Novantrone®
Paclitaxel	Onxol™, Taxol®
Procarbazine	Matulane®
Teniposide	Vumon®
Thioguanine (6-TG)	Tabloid®
Thiotepa	Thiotepa®
Vinblastine	N/A
Vincristine	Vincasar® PFS
Vinorelbine	Navelbine®

4 . Endnotes

A. Currently there is no information available about the effect of longer acting pegylated G-CSF in patients with myeloid leukemias, therefore pegylated G-CSF should not be used in such patients outside of clinical trials. [17]
B. The safety and efficacy of Leukine in AML induction or consolidation in adults younger than 55 years old have not been established in clinical trials. [3]
C. Per hematology/oncology consultant and member of P&T, most cycles of induction or consolidation chemotherapy last ~ 1 month, but patients who complete therapy typically receive 1 induction and 2-3 consolidations, so re-approval would need to occur every month.
D. The safety and efficacy of pegylated G-CSF has not been fully established in the setting of dose-dense chemotherapy. [17]
E. Per hematology/oncology consultant and member of P&T, in general, dose-dense regimens require growth factor support for chemotherapy administration. [16] Also, Neulasta is commonly used to support dose dense regimens in current community practice. It would be reasonable to allow Neulasta use [in the INT C9741 Protocol] and to broaden its use for other forms of dose dense chemotherapy.
F. The product information for both PEG-Intron and Pegasys recommends dose reduction in patients with neutropenia with an ANC level < 750 cells/mm^3. [21, 22]
G. Per GI consultant and member of P&T, his medical group of practicing hepatologists recommends Neupogen for a special subpopulation of patients with HIV infection, status post liver transplant, or established cirrhosis who experience interferon-induced neutropenia (ANC less than or equal to 500 cells/mm^3) due to treatment with Peg-Intron or Pegasys.
H. Guidelines issued by the U.S. Public Health Service (USPHS) and the Infectious Diseases Society of America (IDSA) recommend for HIV-related neutropenia, the length of therapy with G-CSF and GM-CSF is 2-4 weeks. The clinical benefit of G-CSF therapy

was evaluated in a randomized, double-blind, placebo controlled trial of 30 patients evaluating G-CSF 03 mg/mL subcutaneously 3 times a week or placebo for 12 weeks. The 6 month approval duration mirrors the 6 month approval duration for the erythropoietic agents, as G-CSF has been effective when used alone or in conjunction with epoetin alfa in adults with acquired immunodeficiency syndrome (AIDS) to ameliorate the hematologic toxicity (severe anemia and/or granulocytopenia) associated with zidovudine therapy. [11, 15, 37]

I. Note: This list is NOT inclusive of all chemotherapy regimens with a high risk of FN: See Table 2 in Background section
J. Note: This list is NOT inclusive of all chemotherapy regimens with an intermediate risk of FN: See Table 3 in Background section
K. Risk factors are based on provider information, not the list in the table below. Examples of risk factors may include (but are NOT limited to): Risk factors associated with chemotherapy-induced infection, FN, or neutropenia • Age > 65 years [16, 17] • History of extensive prior chemotherapy or radiation therapy including large radiation ports [16, 17] • Previous episodes of FN [16, 17] • Administration of combined chemoradiotherapy [17] • Pre-existing neutropenia or bone marrow involvement with tumor [16, 17] • Pre-existing conditions [16] • Neutropenia • Active infection/open wounds • Recent surgery • Poor performance status [16, 17] • Poor renal function [16] • Liver dysfunction [16] • Poor nutritional status [17] • More advanced cancer [17] • Hypotension and multiorgan dysfunction (Sepsis syndrome) [16, 17] • Pneumonia [16] • Invasive fungal infection [16, 17] • Other clinically documented infections [16] • Hospitalization at the time of fever [16] • Anticipated prolonged (> 10 days) and profound neutropenia (< 100/mm^3) [17] • Uncontrolled primary disease [17] • Other serious comorbidities [17]
L. Note: This list is NOT all inclusive: See Table 4 in Background section
M. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [33] The American Society of Clinical Oncology states that pegfilgrastim, filgrastim, tbo-filgrastim, and filgrastim-sndz (and other biosimilars as they become available) can be used for the prevention of treatment-related febrile neutropenia. The choice of agent depends on convenience, cost, and clinical situation. [34] NCCN lists FDA-approved biosimilars as appropriate substitutes for filgrastim and pegfilgrastim. Limited data suggest that patients can alternate between the biosimilar and the originator biologic without any clinically meaningful differences regarding efficacy or safety. [16]
N. The efficacy of G-CSFs or GM-CSF for the acute radiation syndrome setting was studied in non-human primate models of radiation injury measuring 60-day survival. An expert panel convened by the World Health Organization recommends that patients receive G-CSF or GM-CSF treatment until their absolute neutrophil count reaches and maintains a level greater than 1.0 x 10^9 cells per liter in the absence of active infection. Patients with severe hematopoietic injury may recover, either spontaneously or after G-CSF treatment alone. In most cases, a duration of two to three weeks would be expected. [1-3, 36]

5 . References

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6 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Cometriq (cabozantinib)

Prior Authorization Guideline

Guideline ID	GL-229101
Guideline Name	Cometriq (cabozantinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/19/2013
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Cometriq (cabozantinib)
Medullary thyroid cancer Indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC). **Off Label Uses: Non-small cell lung cancer** Has activity against RET gene rearrangements in non-small cell lung cancer (NSCLC). [3]

2 . Criteria

Product Name:Cometriq

Diagnosis	Medullary Thyroid Cancer (MTC)
Approval Length	11 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COMETRIQ	CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT	21533010106460	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT	21533010106470	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT	21533010106480	Brand

Approval Criteria

1 - Diagnosis of one of the following: [1,2]

- Metastatic medullary thyroid cancer (MTC)
- Unresectable locally advanced MTC

AND

2 - One of the following: [2]

- Patient has symptomatic disease
- Patient has progressive disease

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Cometriq	
Diagnosis	Medullary Thyroid Cancer (MTC)
Approval Length	11 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

COMETRIQ	CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT	21533010106460	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT	21533010106470	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT	21533010106480	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Cometriq	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC) (off-label)
Approval Length	11 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COMETRIQ	CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT	21533010106460	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT	21533010106470	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT	21533010106480	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC) [3]

AND

2 - Presence of RET gene rearrangements as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [3]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Cometriq	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC) (off-label)
Approval Length	11 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COMETRIQ	CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT	21533010106460	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT	21533010106470	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT	21533010106480	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	If patient meets criteria above, please approve at GPI-12.

3 . Endnotes

A. In a phase 3 clinical trial of 330 patients, a statistically significant prolongation in progression free survival (PFS) was demonstrated among Cometriq-treated patients compared to those receiving placebo, with a median PFS time of 11.2 months and 4 months in the Cometriq and placebo arms, respectively. [1]

4 . References

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5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-229103
Guideline Name	Commercial MEDLIMIT CDUR Criteria
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/16/2017
P&T Revision Date:	10/16/2024

1 . Criteria

Product Name:Requested opioid pain medication	
Diagnosis	Level of Care Change
Approval Length	1 Time(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
morphine			
opioid			
MED			

cumulative			
MEE			

Approval Criteria

1 - Provider confirms replacement prescription(s) of opioid medication(s) is needed because the patient is physically changing locations and cannot take their prescription with them [such as admission to a long term care (LTC) facility]

Product Name:Requested opioid pain medication	
Diagnosis	Cancer-Related Pain or Sickle Cell Anemia
Approval Length	12 Months to override MME edit
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - Confirmation opioids are being used for the treatment of cancer-related pain or sickle cell anemia

Product Name:Requested opioid pain medication	
Diagnosis	Hospice, Long Term Care, or End-of-Life Care Enrollment
Approval Length	12 Months to override MME edit
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - Patient is currently enrolled in hospice, end-of-life care, or resides in a long term care facility

Product Name:Requested opioid pain medication

Diagnosis	Other Pain
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - A written or verbal supporting statement is received from the requesting prescriber attesting that in his/her clinical judgment, the requested dose exceeding the current cumulative morphine milligram equivalent (MME) threshold* is medically required

Notes	*MME is calculated using all of the member's current opioid prescriptions *Note: Ask provider, "Will there be a dose escalation in the patient's opioid utilization in the next 90 days?" If yes, approve MME level 90 daily MME above the rejected level.

2 . Endnotes

A. All opioid medication edits are subject to review and modification (either to increase or decrease existing MME Limits) based on an Exception request received from the member or the member's provider. The decision to remove, modify, or retain an existing restriction on opioid pain medications will be based on evidence of new clinical information which is documented in the form of a written supporting statement received from the prescriber and which contains all of the required elements as outlined in the criteria above.

3 . References

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3. Jamison, Robert. Substance abuse treatment for high risk chronic pain patients on opioid therapy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 7/22/2011. Available from: http://clinicaltrials.gov/ct2/show/NCT00988962. NCT00988962. Accessed August 31, 2023.

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4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228823
Guideline Name	Compounded Drugs
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Compounded drugs**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Compound	compound		
Compounds	compounds		
Bulk powders	bulk powders		
COMPOUNDS	COMPOUNDS		
COMPOUNDED DRUGS	COMPOUNDED DRUGS		

COMPOUND	COMPOUND		
COMPOUNDS	COMPOUNDS		

Approval Criteria

1 - Each active ingredient in the compounded drug is FDA-approved or national compendia* supported for the condition being treated

AND

2 - The therapeutic amounts are supported by national compendia* or two peer-reviewed literature for the condition being treated in the requested route of delivery

AND

3 - If a drug included in the compound requires prior authorization and/or step therapy or is non-formulary, all drug-specific criteria must be met

AND

4 - The compounded drug must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (refer to Table 1)

AND

5 - The patient has tried and failed therapy or had an intolerance to two FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met:

5.1 Patient has a contraindication to commercially available products

OR

5.2 One or no other therapeutic alternatives are commercially available

OR

5.3 Prepared in a strength not commercially available or currently in short supply

OR

5.4 Prepared in a different dosage form for a patient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does NOT meet this criteria).

OR

5.5 Patient has an allergy or sensitivity to inactive ingredients (e.g. dyes, preservatives, sugars, etc.) that are found in commercially available products.

AND

6 - The compounded drug must not be used for a cosmetic purpose.

AND

7 - If the compound is subject to the drug-specific/targeted compound program, the member meets all the applicable drug-specific criteria below for all the targeted ingredient(s) used in the requested compound product.

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. *Approved national compendia are referenced in the "Coverage of Off -Label or Non-FDA Approved Indications" Guideline **Administrative guideline may not apply to all compound reviews, dep ending on the ingredients being used and client elections.

Product Name:Diclofenac compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Diclofenac bulk powder			
Diclofenac Ophthalmic Solution			
Arthrotec			
Cambia			
Zorvolex Oral Capsules			
Zipsor Liquid Filled Capsules			
Diclofenac tablets			
Diclofenac tablets			
Dyloject			
Voltaren			
Solaraze			
Pennsaid			
Flector			
Rexaphenac			

Approval Criteria

1 - Compounded drugs that include diclofenac will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Mild to moderate pain
- Pain due to minor strains, sprains or contusions
- Migraine

- Primary dysmenorrhea
- Actinic keratosis
- Ankylosing spondylitis
- Inflammatory disorder of the eye
- Photophobia
- Pain in the eye

AND

1.3 The final dosage form will be for oral, topical, or ophthalmic use

AND

1.4 The final dosage form and strength of the diclofenac ingredient is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the diclofenac targeted compound program.

Product Name:Flurbiprofen compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Flurbiprofen tablets			
Ocufen			
Flurbiprofen bulk powder			

Approval Criteria

1 - Compounded drugs that include flurbiprofen will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Intraoperative miosis inhibition

AND

1.3 The final dosage form will be for oral or ophthalmic use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the flurbiprofen targeted compound program.

Product Name:Fluticasone compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Fluticasone bulk powder			
Cutivate			

Approval Criteria

1 - Compounded drugs that include fluticasone will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 3 months of age or older

AND

1.2 Diagnosis of Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.5 The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the fluticasone targeted compound program.

Product Name:Gabapentin compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Gabapentin bulk powder			
Gralise			
Horizant			
Neurontin			

Approval Criteria

1 - Compounded drugs that include gabapentin will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 3 years of age or older

AND

1.2 Patient must have one of the following diagnoses:

- Partial seizures
- Postherpetic neuralgia
- Restless leg syndrome (RLS)

AND

1.3 The final dosage form will be for oral use

AND

1.4 The requested dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available)

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the gabapentin targeted compound program.

Product Name:Ketamine compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Ketamine bulk powder			
Ketalar			

Approval Criteria

1 - Compounded drugs that include ketamine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 16 years of age or older

AND

1.2 One of the following:

1.2.1 Patient is requiring ketamine for conscious sedation prior to a diagnostic or surgical procedure that do not require skeletal muscle relaxation

OR

1.2.2 Patient is requiring ketamine for the induction of anesthesia prior to the administration of other general anesthetic agents

OR

1.2.3 Patient is requiring ketamine as a supplement to low-potency anesthetic agents, such as nitrous oxide

AND

1.3 The final dosage form will be for injection

AND

1.4 The requested dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.6 The requested dose does not exceed the concentration limit of 100mg/mL*

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. *According to the prescribing information, 100mg/ml product must be

	diluted prior to administration. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the ketamine targeted compound program.

Product Name:Ketoprofen compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Ketoprofen bulk powder			
Ketoprofen extended-release capsules			
Ketoprofen capsules			

Approval Criteria

1 - Compounded drugs that include ketoprofen will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Acute pain
- Primary dysmenorrhea

AND

1.3 The final dosage form will be for oral use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the ketoprofen targeted compound program.

Product Name:Levocetirizine compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Levocetirizine bulk powder			
Xyzal			

Approval Criteria

1 - Compounded drugs that include levocetirizine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 6 months of age or older

AND

1.2 Diagnosis of one of the following:

- Seasonal or perennial allergic rhinitis
- Uncomplicated skin manifestations of chronic idiopathic urticaria

AND

1.3 The final dosage form will be for oral use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the levocetirizine targeted compound program.

Product Name:Mometasone compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Mometasone powder			
Elocon			

Approval Criteria

1 - Compounded drugs that include mometasone will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 2 years of age or older

AND

1.2 Diagnosis of Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.5 The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the mometasone targeted compound program.

Product Name:Acyclovir ointment 5% compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Acyclovir 5% Topical Ointment			
Zovirax 5% Topical Ointment			

Approval Criteria

1 - Compounded drugs that include Acyclovir ointment 5% will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis for one of the following:

- Management of initial genital herpes
- Limited non-life-threatening mucutaneous herpes simplex virus infection in immunocompromised patients

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available)

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the Acyclovir ointment 5% targeted compound program.

Product Name:Doxepin cream 5% compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Doxepin 5% Topical Cream			
Prudoxin 5% Topical Cream			
Zonalon 5% Topical Cream			

Approval Criteria

1 - Compounded drugs that include Doxepin cream 5% will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Treatment of moderate pruritus with atopic dermatitis or lichen simplex chronicus

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available)

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the Doxepin cream 5% targeted compound program.

2 . Background

Benefit/Coverage/Program Information

Table 1: Drugs that were withdrawn from the market due to safety or effectiveness

3,3',4',5-tetrachlorosalicylanilide	Methopholine Methoxylflurane
Adenosine phosphate	Methoxyflurane
Adrenal cortex	Mibefradil dihydrochloride
Alatrofloxacin mesylate	Nitrofurazone
Aminopyrine	Nomifensine maleate
Astemizole	Novobiocin
Azaribine	Ondansetron hydrochloride
Benoxaprofen	Oxyphenisatin
Bithionol	Oxyphenisatin acetate
Bromfenac sodium	Pemoline
Bromocriptine mesylate	Pergolide mesylate
Butamben	Phenacetin
Camphorated oil	Phenformin hydrochloride
Carbetapentane citrate	Phenylpropanolamine
Casein, iodinated	Pipamazine
Cerivastatin sodium	Polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride, and bisacodyl
Chloramphenicol	

Chlorhexidine gluconate	Potassium arsenite
Chlormadinone acetate	Potassium chloride
Chloroform	Povidone
Cisapride	Propoxyphene
Cobalt	Rapacuronium bromide
Dexfenfluramine hydrochloride	Reserpine
Diamthazole dihydrochloride	Rofecoxib
Dibromsalan	Sibutramine hydrochloride
Diethylstilbestrol	Sparteine sulfate
Dihydrostreptomycin sulfate	Sulfadimethoxine
Dipyrone	Sulfathiazole
Encainide hydrochloride	Suprofen
Esmolol hydrochloride	Sweet spirits of nitre
Etretinate	Tegaserod maleate
Fenfluramine hydrochloride	Temafloxacin hydrochloride
Flosequinan	Terfenadine
Gatifloxacin	Tetracycline
Gelatin	Ticrynafen
Glycerol, iodinated	Tribromsalan
Gonadotropin, chorionic	Trichloroethane
Grepafloxacin	Troglitazone
Mepazine	Trovafloxacin mesylate

Metabromsalan	Urethane
Methamphetamine hydrochloride	Valdexocib
Methapyrilene	Vinyl chloride
	Zirconium
	Zomepirac sodium

Diclofenac Compounds

There is little to no evidence-based literature support for the use of diclofenac for indications and in dosage forms not currently approved by the FDA. Use of compounds containing diclofenac should be limited to the following FDA-approved indications.

1. Diclofenac is indicated for a number of conditions including:
• Management of mild to moderate acute pain or osteoarthritis pain,
• Relief of signs and symptoms of ankylosing spondylitis and rheumatoid arthritis
• Relieve acute pain associated with minor sprains, strains, and contusions
• Treatment of primary dysmenorrhea
• Treatment of acute migraine attacks with or without aura in adults
• Treatment of actinic keratosis
• Treatment of postoperative inflammation in patients who have undergone cataract surgery and temporary relief of pain and photophobia associated with corneal refractive surgery.

2. Safety and efficacy in pediatric populations has not been established.

3. Diclofenac is commercially available in the several dosage forms: oral capsules, oral tablets, oral solution, topical patch, topical gel, topical solution, topical ointment and ophthalmic solution.

Flurbiprofen Compounds

There is little to no evidence-based literature support for the use of flurbiprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing flurbiprofen should be limited to the following FDA-approved indications.

- Flurbiprofen tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Flurbiprofen ophthalmic solution is indication for preventing intraoperative miosis.

- Flurbiprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Flurbiprofen is commercially available as a 50 and 100 mg oral tablet and also as 0.03% sterile ophthalmic solution.

Fluticasone Compounds

There is little to no evidence-based literature support for the use of fluticasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing fluticasone should be limited to the following FDA-approved indications.

- Fluticasone cream indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 3 months of age or older.

Fluticasone is commercially available in the several dosage forms: topical cream, topical lotion, topical ointment, nasal spray and various aerosols and powders for inhalation

Gabapentin Compounds

There is little to no evidence-based literature support for the use of gabapentin for indications or in dosage forms not currently approved by the FDA. Use of compounds containing gabapentin should be limited to the following FDA-approved indications.

- Gabapentin is indicated for treatment postherpetic neuralgia in adults (Gralise prescribing information, 2023; Horizant prescribing information, 2020; Neurontin prescribing information, 2020).
- Gabapentin is indicated as adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy (Neurontin prescribing information, 2020).
- Gabapentin is indicated for the treatment of moderate to severe primary restless leg syndrome (Horizant prescribing information, 2020).

Ketamine Compounds

There is little to no evidence-based literature support for the use of ketamine for indications or in dosage forms not currently approved by the FDA. Use of compounds containing ketamine should be limited to the following FDA-approved indications.

- Ketamine is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation (Ketalar prescribing information, 2022)

- Ketamine is indicated for the induction of anesthesia prior to the administration of other general anesthetic agents (Ketalar prescribing information, 2022)
- Ketamine is indicated to supplement low-potency agents, such as nitrous oxide (Ketalar prescribing information, 2022)
- Esketamine (the S-enantiomer of racemic ketamine) is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults (Spravato prescribing information, 2023). Coverage of compounds with racemic ketamine will continue to be limited to the FDA approved indications listed above.

Ketoprofen Compounds

There is little to no evidence-based literature support for the use of ketoprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing ketoprofen should be limited to the following FDA-approved indications.

- Ketoprofen immediate-release capsules and ketoprofen extended-release capsules are indicated for the management of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Ketoprofen immediate-release capsules are indicated for the management of pain and for treatment of primary dysmenorrhea.
- Ketoprofen extended-release capsules are not recommended for treatment of acute pain because of its extended-release characteristics.
- Ketoprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Ketoprofen is commercially available as a 50 and 75 mg oral capsule and 200 mg extended release oral capsule.

Levocetirizine Compounds

There is little to no evidence-based literature support for the use of levocetirizine for indications and in dosage forms not currently approved by the FDA. Use of compounds containing levocetirizine should be limited to the following FDA-approved indications.

- Levocetirizine dihydrochloride, a histamine (H1) receptor antagonist, is indicated for:
    - Treatment of perennial allergic rhinitis in adults and children 6 months of age or older.
    - Treatment of seasonal allergic rhinitis in adults and children 2 years of age and older
    - Uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older

- Levocetirizine is commercially available as a 5 mg oral tablet and 2.5 mg/mL oral solution.

Mometasone Compounds

There is little to no evidence-based literature support for the use of mometasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing mometasone should be limited to the following FDA-approved indications.

- Mometasone cream & ointment are indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥ 2 years of age.
- Mometasone lotion is indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥12 years of age.
- Mometasone is commercially available in several dosage forms: topical cream, topical lotion, topical ointment, nasal spray, powder for inhalation and sinus implant.

Acyclovir ointment 5% Compounds

There is little to no evidence-based literature support for the use of Acyclovir ointment 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Acyclovir ointment 5% should be limited to the following FDA-approved indications.

- Acyclovir ointment 5% is indicated for the management of initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infection in immunocompromised patients.
- Acyclovir is commercially available in several dosage forms: topical ointment, topical cream, buccal tablet, tablet, capsule, oral suspension, and intravenous solution.

Doxepin cream 5% Compounds

There is little to no evidence-based literature support for the use of Doxepin cream 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Doxepin cream 5% should be limited to the following FDA-approved indications.

- Doxepin cream 5% is indicated for short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.
- Doxepin cream 5% is commercially available in several dosage forms: topical cream, capsule, tablet, and oral concentrate

3 . Endnotes

A. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. [1]
B. Compound drugs are customized in the following ways to meet patients need: (1) Removal of a nonessential ingredient for patients' allergies; and (2) Change in medication formulation (e.g., pill to solution in a patient with swallowing difficulties). [1]
C. Benefit design recommendations provided in the OptumRx Commercial Implementation Guide: (1) $200 Rx High Dollar Limit at Retail; (2) The processing of compound drugs will be subject to the same benefit plan edits: day supply, copay and drug coverage; (3) Multiple ingredient processing is recommended; (4) Bulk chemicals and compound kit recommended as standard exclusions.
D. Compounding does not generally include mixing or reconstituting commercially available products in accordance with the manufacturer’s instructions or the product’s approved labeling.

4 . References

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7. Horizant prescribing information. Arbor Pharmaceuticals, LLC. Atlanta, GA. April 2020.
8. Neurontin prescribing information. Pfizer. New York, NY. December 2020.
9. Ketalar prescribing information. Par Pharmaceutical. Chestnut Ridge, NY. June 2022.
10. Ketoprofen Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. March 2021.
11. Spravato Prescribing Information. Janssen Pharmaceuticals. Titusville, NJ. October 2023.
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5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233383
Guideline Name	Constipation Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	8/18/2008
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Amitiza (lubiprostone)
Chronic Idiopathic Constipation (CIC) Indicated for the treatment of CIC in adults. **Opioid-Induced Constipation in Adult Patients with Chronic Non-Cancer Pain** Indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Limitations of Use: Effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking diphenylheptane opioids (e.g., methadone) has not been established. **Irritable Bowel Syndrome with Constipation** Indicated for the treatment of irritable bowel syndrome with constipation in women at least 18 years old.
Drug Name: Linzess (linaclotide)

Irritable Bowel Syndrome with Constipation (IBS-C) Indicated in adults for the treatment of irritable bowel syndrome with constipation (IBS-C).

CIC Indicated in adults for the treatment of CIC.

Functional Constipation (FC) Indicated in pediatric patients 6 to 17 years of age for the treatment of functional constipation (FC).

Drug Name: Movantik (naloxegol)

Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Drug Name: Motegrity (prucalopride)

CIC Indicated for the treatment of CIC in adults.

Drug Name: Relistor (methylnaltrexone bromide) injection

Opioid-Induced Constipation (advanced illness or pain caused by active cancer) [1, 2] Indicated for the treatment of OIC in adult patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Drug Name: Relistor (methylnaltrexone bromide) tablet

Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Drug Name: Symproic (naldemedine)

Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Drug Name: Trulance (plecanatide)

CIC Indicated in adults for the treatment of CIC.

IBS-C Indicated in adults for the treatment of IBS-C.

2 . Criteria

Product Name:Brand Amitiza	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
AMITIZA	LUBIPROSTONE CAP 8 MCG	52450045000110	Brand
AMITIZA	LUBIPROSTONE CAP 24 MCG	52450045000120	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]

- Lactulose
- Polyethylene glycol

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following preferred brands: [B]

- Linzess
- Movantik

- Symproic

Product Name:Linzess, Movantik, Symproic, generic prucalopride	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
MOVANTIK	NALOXEGOL OXALATE TAB 12.5 MG (BASE EQUIVALENT)	52580060300320	Brand
MOVANTIK	NALOXEGOL OXALATE TAB 25 MG (BASE EQUIVALENT)	52580060300330	Brand
SYMPROIC	NALDEMEDINE TOSYLATE TAB 0.2 MG (BASE EQUIVALENT)	52580057200320	Brand
LINZESS	LINACLOTIDE CAP 72 MCG	52557050000110	Brand
LINZESS	LINACLOTIDE CAP 145 MCG	52557050000120	Brand
LINZESS	LINACLOTIDE CAP 290 MCG	52557050000140	Brand
PRUCALOPRIDE	PRUCALOPRIDE SUCCINATE TAB 1 MG (BASE EQUIVALENT)	52560060200320	Generic
PRUCALOPRIDE	PRUCALOPRIDE SUCCINATE TAB 2 MG (BASE EQUIVALENT)	52560060200330	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]

- Lactulose
- Polyethylene glycol

Product Name:Brand Motegrity, Trulance	
Approval Length	12 month(s)

Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TRULANCE	PLECANATIDE TAB 3 MG	52543060000320	Brand
MOTEGRITY	PRUCALOPRIDE SUCCINATE TAB 1 MG (BASE EQUIVALENT)	52560060200320	Brand
MOTEGRITY	PRUCALOPRIDE SUCCINATE TAB 2 MG (BASE EQUIVALENT)	52560060200330	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]

- Lactulose
- Polyethylene glycol

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to Linzess

AND

4 - For Trulance, trial and failure (of a minimum 30 days supply), contraindication, or intolerance to generic lubiprostone

Product Name:Relistor injection, Relistor tablet	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
RELISTOR	METHYLNALTREXONE BROMIDE INJ 12 MG/0.6ML (20 MG/ML)	52580050102020	Brand
RELISTOR	METHYLNALTREXONE BROMIDE INJ 8 MG/0.4ML (20 MG/ML)	52580050102015	Brand
RELISTOR	METHYLNALTREXONE BROMIDE TAB 150 MG	52580050100320	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]

- Lactulose
- Polyethylene glycol

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following preferred brands: [B]

- Movantik
- Symproic

AND

4 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to generic lubiprostone

3 . Endnotes

A. Stimulant and osmotic laxatives should be tried/failed first before patients are placed on OIC agents (ie, Relistor and Movantik). [2, 3]
B. The 2019 American Gastroenterological Association (AGA) Guideline for Opioid-Induced Constipation (OIC) recommends traditional laxative therapy as first-line agents given their established efficacy, safety, and lower cost. If an adequate trial of laxatives does not optimally control symptoms, the AGA recommends treatment with peripherally acting mu-opioid receptor antagonist (PAMORA) drugs with higher quality evidence of efficacy, namely naldemedine and naloxegol. [2]

4 . References

1. Relistor Prescribing Information. Salix Pharmaceuticals. Bridgewater, NJ. April 2020.
2. Per clinical consult with gastroenterologist, February 19, 2019.
3. Crockett SD, Greer KB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. Gastroenterology. Gastroenterology. 2019;156:218-226.
4. Movantik Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. April 2020.
5. Symproic Prescribing Information. BioDelivery Sciences International Inc. Raleigh, NC. July 2021.
6. Linzess Prescribing Information. Allergan USA, Inc. Madison, NJ. June 2023.
7. Trulance Prescribing Information. Salix Pharmaceuticals Inc. Bridgewater, NJ. April 2021.
8. Amitiza Prescribing Information. Takeda Pharmaceuticals America, Inc. Deerfield, IL. November 2020.
9. Motegrity Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. November 2020.
10. Ford AC, Moayyedi P, Chey WD, Harris LA, Lacy BE, Saito YA, Quigley EMM; ACG Task Force on Management of Irritable Bowel Syndrome. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. Am J Gastroenterol. 2018 Jun;113(Suppl 2):1-18.

5 . Revision History

Date	Notes
3/13/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-228391
Guideline Name	Continuous Glucose Monitors, Sensors, and Transmitters - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Dexcom Products*, Freestyle Libre Products*			
Approval Length	12 month(s)		
Therapy Stage	Initial Authorization		
Guideline Type	Prior Authorization		

Product Name	Generic Name	GPI	Brand/Generic
DEXCOM G6 RECEIVER	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 14 DAY/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 2/READER/FLASH	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand

GLUCOSE MONITORING SYSTEM			
FREESTYLE LIBRE/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
DEXCOM G6 SENSOR	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 14 DAY/SENSOR/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 2/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
DEXCOM G6 TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
DEXCOM G7 SENSOR	CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
DEXCOM G7 RECEIVER	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 3/READER/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 3/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 3 PLUS/SESOR/GLUCOSE MONITORING SYSTEM	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of diabetes mellitus

AND

1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support

AND

1.3 ONE of the following:

1.3.1 Patient is being treated with insulin

OR

1.3.2 Patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan
- Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

Notes	*If patient meets criteria above, please approve all CGM components at NDC list “PREFCGMPA”

Product Name:Dexcom Products*, Freestyle Libre Products*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEXCOM G6 RECEIVER	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 14 DAY/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 2/READER/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
DEXCOM G6 SENSOR	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand

FREESTYLE LIBRE 14 DAY/SENSOR/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 2/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
DEXCOM G6 TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
DEXCOM G7 SENSOR	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
DEXCOM G7 RECEIVER	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 3/READER/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 3/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 3 PLUS/SESOR/GLUCOSE MONITORING SYSTEM	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand

Approval Criteria

1 - ONE of the following:

1.1 Patient demonstrates positive clinical response as evidenced by ONE of the following:

- Improvement in glycemic control (e.g., lower and/or maintain A1C levels)
- Reduction or improvement in hypoglycemic events

OR

1.2 Patient is being assessed by the prescriber for adherence to their CGM regimen and diabetes treatment plan

Notes	*If patient meets criteria above, please approve all CGM components at NDC list “PREFCGMPA”

Product Name:All Other Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GUARDIAN REAL-TIME REPLACEMENT MONITOR PEDIATRIC	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
ENLITE GLUCOSE SENSOR	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE SENSOR/HOLDER	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN SENSOR (3)	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN SENSOR 3	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE SMART TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN CONNECT TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN CONNECT TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN LINK 3 TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINILINK REAL-TIME TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINIMED GUARDIAN LINK 3 TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINIMED 630G GUARDIAN PRESS STARTER TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
PARADIGM REAL-TIME TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
BIGFOOT UNITY PROGRAM KIT	*BLOOD GLUCOSE MONITOR KIT W/ MONITOR DEVICE & DIGITAL APP**	97202010006419	Brand
EVERSENSE E3 SENSOR/HOLDER	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand

EVERSENSE E3 SMART TRANSMITTER	*CONTINUOUS GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN 4 GLUCOSE SENSOR	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN 4 TRANSMITTER KIT	*CONTINUOUS GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of diabetes mellitus

AND

1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support

AND

1.3 ONE of the following:

1.3.1 Patient is being treated with insulin

OR

1.3.2 Patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan
- Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

AND

1.4 Both of the following:

1.4.1 Minimum 90 day trial within the last 180 days, to both of the following:

- Dexcom Products
- Freestyle Products

AND

1.4.2 Valid clinical rationale provided, explaining how the requested device is the only product that will provide benefit when the Dexcom and Freestyle products have not shown to be effective

Notes	*If patient meets criteria above, please approve all CGM components at GPI list “CGMPA”

Product Name:All Other Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GUARDIAN REAL-TIME REPLACEMENT MONITOR PEDIATRIC	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
ENLITE GLUCOSE SENSOR	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE SENSOR/HOLDER	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN SENSOR (3)	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN SENSOR 3	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE SMART TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN CONNECT TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN CONNECT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand

TRANSMITTER KIT			
GUARDIAN LINK 3 TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINILINK REAL-TIME TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINIMED GUARDIAN LINK 3 TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINIMED 630G GUARDIAN PRESS STARTER TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
PARADIGM REAL-TIME TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
BIGFOOT UNITY PROGRAM KIT	*BLOOD GLUCOSE MONITOR KIT W/ MONITOR DEVICE & DIGITAL APP**	97202010006419	Brand
EVERSENSE E3 SENSOR/HOLDER	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE E3 SMART TRANSMITTER	*CONTINUOUS GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN 4 GLUCOSE SENSOR	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN 4 TRANSMITTER KIT	*CONTINUOUS GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand

Approval Criteria

1 - ONE of the following:

1.1 Patient demonstrates positive clinical response as evidenced by ONE of the following:

- Improvement in glycemic control (e.g., lower and/or maintain A1C levels)
- Reduction or improvement in hypoglycemic events

OR

1.2 Patient is being assessed by the prescriber for adherence to their CGM regimen and diabetes treatment plan

AND

2 - Minimum 90 day trial to both of the following:

- Dexcom Products
- Freestyle Products

Notes	*If patient meets criteria above, please approve all CGM components at GPI list “CGMPA”

Product Name:Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EVERSENSE SENSOR/HOLDER	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE SMART TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
BIGFOOT UNITY PROGRAM KIT	*BLOOD GLUCOSE MONITOR KIT W/ MONITOR DEVICE & DIGITAL APP**	97202010006419	Brand
FREESTYLE LIBRE 14 DAY/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 2/READER/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 14 DAY/SENSOR/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 2/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 3/READER/FLASH	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand

GLUCOSE MONITORING SYSTEM			
FREESTYLE LIBRE 3/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE E3 SENSOR/HOLDER	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE E3 SMART TRANSMITTER	*CONTINUOUS GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
FREESTYLE LIBRE 3 PLUS/SENSOR/GLUCOSE MONITORING SYSTEM	CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of diabetes mellitus

AND

1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support

AND

1.3 ONE of the following:

1.3.1 Submission of medical records (e.g., chart notes) or paid claims confirming patient is being treated with insulin

OR

1.3.2 Submission of medical records (e.g., chart notes) confirming patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan

• Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia **AND** **1.4** Both of the following (Applies to all products except Dexcom): **1.4.1** Submission of medical records (e.g., chart notes) or paid claims confirming minimum 90 day trial within the last 180 days, to Dexcom products **AND** **1.4.2** Submission of medical records (e.g., chart notes) providing valid clinical rationale explaining how the requested device is the only product that will provide benefit when Dexcom products have not shown to be effective	
Notes	*If patient meets criteria above, please approve all CGM components at GPI list “CGMPA”

2 . Endnotes

A. People who have been using continuous glucose monitoring, continuous subcutaneous insulin infusion, and/or automated insulin delivery for diabetes management should have continued access across third party payers. Interruption of access to CGM is associated with a worsening of outcomes, therefore, it is important for individuals on CGM to have consistent access. [2]

3 . References

1. CMS. Provider compliance tips for glucose monitors & diabetic accessories/supplies. CMS Website. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822. Accessed March 21, 2023.
2. American Diabetes Association. Diabetes Care. Available at Volume 45 Issue Supplement_1 Diabetes Care | American Diabetes Association (diabetesjournals.org). Available at https://diabetesjournals.org/care/issue/45/Supplement_1. Accessed April 12, 2022.
3. BigFoot Unity PDF. Available at: https://f.hubspotusercontent40.net/hubfs/5085144/PDFs/Bigfoot%20Unity%E2%84%A2%20System%20User%20Guide.pdf. Accessed May 23, 2023.

Prior Authorization Guideline

Guideline ID	GL-229173
Guideline Name	Copiktra (duvelisib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/15/2018
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Copiktra (duvelisib)
Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies.

2 . Criteria

Product Name:Copiktra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COPIKTRA	DUVELISIB CAP 15 MG	21538030000120	Brand
COPIKTRA	DUVELISIB CAP 25 MG	21538030000130	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

AND

2 - Disease is relapsed or refractory

AND

3 - Trial and failure, contraindication, or intolerance to at least two prior therapies for CLL/SLL (e.g., Leukeran [chlorambucil], Calquence [acalabrutinib], Gazyva [obinutuzumab], Arzerra [ofatumumab], Venclexta [venetoclax], Bendeka [bendamustine], Imbruvica [ibrutinib], Rituxan [rituximab], etc.) [2]

Product Name:Copiktra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COPIKTRA	DUVELISIB CAP 15 MG	21538030000120	Brand
COPIKTRA	DUVELISIB CAP 25 MG	21538030000130	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Copiktra Prescribing Information. Verastem, Inc. Needham, MA. July 2024.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma v1.2025. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed November 5, 2024

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-229107
Guideline Name	Copper Chelating Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	8/20/2014
P&T Revision Date:	6/19/2024

1 . Indications

Drug Name: Cuprimine (penicillamine)
Wilson's Disease Indicated in the treatment of Wilson's disease. **Cystinuria** Indicated in the treatment of cystinuria. **Rheumatoid Arthritis** Indicated in the treatment of severe, active rheumatoid arthritis in patients who have failed to respond to an adequate trial of conventional therapy.
Drug Name: Syprine (trientine)
Wilson's Disease Indicated in the treatment of patients with Wilson's disease who are intolerant of penicillamine.
Drug Name: Cuvrior (trientine tetrahydrochloride)

Wilson's Disease Indicated for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine.

2 . Criteria

Product Name:Brand Cuprimine, generic penicillamine	
Diagnosis	Wilson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Documentation of one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg
- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist

Product Name:Brand Cuprimine, generic penicillamine	
Diagnosis	Cystinuria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Diagnosis of cystinuria

AND

2 - Trial and failure, contraindication, or intolerance to both of the following:

- Urinary alkalinization therapy [4]
- Thiola (tiopronin) [A]

AND

3 - Trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Urologist

Product Name:Brand Cuprimine, generic penicillamine	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Diagnosis of severe, active rheumatoid arthritis

AND

2 - Patient's condition is unresponsive to conventional therapy [e.g., traditional DMARDs (e.g., methotrexate, sulfasalazine), TNF inhibitor (e.g., Humira (adalimumab), Enbrel (etanercept)), Non-TNF biologic (e.g., Rinvoq (upadacitinb), Xeljanz (tofacitinib)]

AND

3 - Trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name:Brand Cuprimine, generic penicillamine	
Diagnosis	Wilson's disease, Cystinuria, Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Brand Cuprimine, generic penicillamine	
Diagnosis	Wilson's Disease
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg
- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist

Product Name:Brand Cuprimine, generic penicillamine	
Diagnosis	Cystinuria
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Diagnosis of cystinuria

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

- Urinary alkalinization therapy [4]
- Thiola (tiopronin) [A]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Urologist

Product Name:Brand Cuprimine, generic penicillamine	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Diagnosis of severe, active rheumatoid arthritis

AND

2 - Patient's condition is unresponsive to conventional therapy [e.g., traditional DMARDs (e.g., methotrexate, sulfasalazine), TNF inhibitor (e.g., Humira (adalimumab), Enbrel (etanercept)), Non-TNF biologic (e.g., Rinvoq (upadacitinb), Xeljanz (tofacitinib)]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name:Brand Syprine, generic trientine, Cuvrior	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYPRINE	TRIENTINE HCL CAP 250 MG	99200020100110	Brand
TRIENTINE HYDROCHLORIDE	TRIENTINE HCL CAP 250 MG	99200020100110	Generic
CUVRIOR	TRIENTINE TETRAHYDROCHLORIDE TAB 300 MG	99200020200330	Brand
TRIENTINE HYDROCHLORIDE	TRIENTINE HCL CAP 500 MG	99200020100130	Generic

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Documentation of one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg
- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Trial and failure, contraindication, or intolerance to Depen (penicillamine) tablets

AND

4 - For Brand Syprine and Cuvrior, trial and failure, or intolerance to generic trientine

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist

Product Name:Brand Syprine, generic trientine, Cuvrior	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYPRINE	TRIENTINE HCL CAP 250 MG	99200020100110	Brand

TRIENTINE HYDROCHLORIDE	TRIENTINE HCL CAP 250 MG	99200020100110	Generic
CUVRIOR	TRIENTINE TETRAHYDROCHLORIDE TAB 300 MG	99200020200330	Brand
TRIENTINE HYDROCHLORIDE	TRIENTINE HCL CAP 500 MG	99200020100130	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - For Brand Syprine and Cuvrior, trial and failure, or intolerance to generic trientine

Product Name:Cuvrior, Brand Syprine	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CUVRIOR	TRIENTINE TETRAHYDROCHLORIDE TAB 300 MG	99200020200330	Brand
SYPRINE	TRIENTINE HCL CAP 250 MG	99200020100110	Brand

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg

- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Depen (penicillamine) tablets

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic trientine

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist

3 . Endnotes

A. Cystine-binding thiol drugs should be offered to patients with cysteine stones who are unresponsive to dietary modification and urinary alkalinization [3]. Tiopronin should be considered first as it is possibly more effective and associated with fewer adverse events than d-penicillamine.

4 . References

1. Cuprimine prescribing information. Bausch Health US, LLC. Bridgewater, NJ. October 2020.
2. Syprine prescribing information. Bausch Health US, LLC. Bridgewater, NJ. September 2020.
3. Pearle MS, Goldfarb DS, Assimos DG, et al. Medical management of kidney stones: AUA guideline. J Urol. 2014 Aug;192(2):316-24.
4. Fattah H, Hambaroush Y, Goldfarb DS. Cystine nephrolithiasis. Transl Androl Urol. 2014 Sep 1;3(3):228-233. doi: 10.3978/j.issn.2223-4683.2014.07.04.

5. European Association for Study of Liver. EASL Clinical Practice Guidelines: Wilson's disease. J Hepatol. 2012;56(3):671-685.
6. Cuvrior Prescribing Information. Orphalan SA. Chicago, IL. May 2022.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Corlanor (ivabradine)

Prior Authorization Guideline

Guideline ID	GL-228826
Guideline Name	Corlanor (ivabradine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Corlanor (ivabradine)
Chronic Heart Failure Indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic, chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use. **Heart Failure due to Dilated Cardiomyopathy (DCM)** Indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate. **Off Label Uses: Inappropriate Sinus Tachycardia (IST)** Has been used for the treatment of inappropriate sinus tachycardia (IST). [7]

2 . Criteria

Product Name:Brand Corlanor, generic ivabradine	
Diagnosis	Chronic Heart Failure
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CORLANOR	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Brand
CORLANOR	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Brand
CORLANOR	IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV)	40700035102020	Brand
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Generic
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Generic

Approval Criteria

1 - Diagnosis of chronic heart failure [3, 5]

AND

2 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms [3, 5, A]

AND

3 - Patient has a left ventricular ejection fraction of less than or equal to 35% [3, 5]

AND

4 - Patient is in sinus rhythm [3, 5]

AND

5 - Patient has a resting heart rate that is greater than or equal to 70 beats per minute [3, 5, E]

AND

6 - Trial and failure, contraindication, or intolerance to all of the following at a maximally tolerated dose: [10]

6.1 One of the following:

- Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)
- Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)]

AND

6.2 One of the following: [3, 5, 10, B-F]

- bisoprolol
- carvedilol
- metoprolol succinate extended-release

AND

6.3 Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformn)]

AND

6.4 Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]

AND

7 - Patient has been hospitalized for worsening heart failure in the previous 12 months [3]

AND

8 - Prescribed by or in consultation with a cardiologist

Product Name:Brand Corlanor, generic ivabradine	
Diagnosis	Heart Failure due to Dilated Cardiomyopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CORLANOR	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Brand
CORLANOR	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Brand
CORLANOR	IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV)	40700035102020	Brand
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Generic
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Generic

Approval Criteria

1 - Diagnosis of heart failure due to dilated cardiomyopathy

AND

2 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms [6]

AND

3 - Patient is in sinus rhythm

AND

4 - Patient has an elevated heart rate

AND

5 - Trial and failure, contraindication, or intolerance to one of the following: [1, 4, 6]

- Beta blocker (e.g., bisoprolol, metoprolol succinate extended release)
- Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Diuretic Agent (e.g., spironolactone, furosemide)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name:Brand Corlanor, generic ivabradine	
Diagnosis	Inappropriate Sinus Tachycardia (IST) [off-label]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CORLANOR	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Brand
CORLANOR	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Brand
CORLANOR	IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV)	40700035102020	Brand
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Generic
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Generic

Approval Criteria

1 - Diagnosis of inappropriate sinus tachycardia (IST) confirmed by both of the following: [7]

- Sinus heart rate greater than 100 beats per minute at rest
- A mean 24 hour heart rate greater than 90 beats per minute

AND

2 - Other causes of sinus tachycardia have been ruled out (e.g., hyperthyroidism, anemia, illicit stimulant drug use, caffeine, etc.) [7]

AND

3 - Provider attests that symptoms of IST are causing significant functional impairment or distress (e.g., palpitations, light-headedness, syncope, chest pain, dyspnea, etc.) [8, 9]

AND

4 - Prescribed by or in consultation with a cardiologist

Product Name:Brand Corlanor, generic ivabradine	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CORLANOR	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Brand
CORLANOR	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Brand
CORLANOR	IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV)	40700035102020	Brand
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Generic
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, patients' heart failure was defined as New York Heart Association class II, III or IV [1, 3]
B. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, the main reasons for not achieving guideline-recommended doses of beta-blocker therapy were hypotension, fatigue, dyspnea, dizziness, history of cardiac decompensation, and bradycardia [1, 3]
C. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, the main reasons that patients were unable to receive beta-blocker therapy were due to a diagnosis of chronic obstructive pulmonary disease, hypotension or asthma [1, 3]
D. The following are examples of contraindications to beta-blocker therapy but is not a comprehensive list: severe bradycardia, decompensated cardiac failure, cardiogenic shock, second-or-third degree heart block, sick sinus syndrome (without a functional permanent pacemaker) [4]
E. Corlanor slows the heart rate by inhibiting the cardiac pacemaker If current and therefore heart rate should be at or above 70 beats per minute prior to initiation of therapy to ensure bradycardia does not ensue following initiation of therapy with Corlanor [2]
F. Per 2022 AHA/ACC/HFSA guideline for the management of Heart Failure, three beta blockers have been shown to be effective in reducing the risk of death in patients with HFrEF: bisoprolol, metoprolol succinate, and carvedilol. [10]

4 . References

1. Corlanor Prescribing Information. Amgen Inc. Thousand Oaks, CA. April 2019.
2. Ivabradine (Corlanor) for heart failure. Med Lett Drugs Ther. 2015 May 25; 57 (1469): 75-6.
3. Swedberg K, Komajda M, Bohm M, et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomized placebo-controlled study. Lancet. 2010 Sep 11;376(9744):875-85.
4. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc; Updated periodically. Available by subscription at: http://www.thomsonhc.com/. Accessed June 25, 2020.
5. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. J Am Coll Cardiol. 2017 Aug 8;70(6):776-803.
6. Bonnet D, Berger F, Jokinen E, et al. Ivabradine in children with dilated cardiomyopathy and symptomatic chronic heart failure. J Am Coll Cardiol. 2017 Sep 5;70(10):1262-1272.
7. Page RL, Joglar JA, Caldwell MA, et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2016 Apr 5;67(13):e27-e115.
8. Cappato R, Castelvecchio S, Ricci C, et al. Clinical efficacy of ivabradine in patients with inappropriate sinus tachycardia: a prospective, randomized, placebo-controlled, double-blind, crossover evaluation. J Am Coll Cardiol. 2012 Oct 9;60(15):1323-9.

9. Sheldon RS, Grubb BP 2nd, Olshansky B, et al. 2015 heart rhythm society expert consensus statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope. Heart Rhythm. 2015 Jun;12(6):e41-63.
10. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. Journal of Cardiac Failure. Published online April 2022.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228394
Guideline Name	Cosela (trilaciclib) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cosela (trilaciclib)
Chemotherapy-induced myelosuppression Indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).

2 . Criteria

Product Name:Cosela	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSELA	TRILACICLIB DIHYDROCHLORIDE FOR IV SOLN 300 MG	21756570202120	Brand

Approval Criteria

1 - Diagnosis of extensive-stage small cell lung cancer (ES-SCLC)

AND

2 - Patient is receiving one of the following anti-cancer chemotherapeutic regimens:

- Platinum/etoposide-containing regimen
- Topotecan-containing regimen

AND

3 - Infusion is completed within 4 hours prior to the start of chemotherapy

AND

4 - The interval between doses on sequential days will not be greater than 28 hours

Product Name:Cosela	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
COSELA	TRILACICLIB DIHYDROCHLORIDE FOR IV SOLN 300 MG	21756570202120	Brand

Approval Criteria

1 - Diagnosis of extensive-stage small cell lung cancer (ES-SCLC)

AND

2 - Patient is receiving one of the following anti-cancer chemotherapeutic regimens:

- Platinum/etoposide-containing regimen
- Topotecan-containing regimen

AND

3 - Infusion is completed within 4 hours prior to the start of chemotherapy

AND

4 - The interval between doses on sequential days will not be greater than 28 hours

3 . References

1. Cosela Prescribing Information. G1 Therapeutics, Inc. Durham, NC. August 2023.

Prior Authorization Guideline

Guideline ID	GL-229082
Guideline Name	Cosentyx (secukinumab) - PA
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Cosentyx SC	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand

COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)

- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name:Cosentyx SC	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction in the BSA involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Cosentyx IV & SC

Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - One of the following:

- Cosentyx SC: Patient is 2 years of age or older
- Cosentyx IV: Patient is 18 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name:Cosentyx IV & SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the BSA involvement from baseline

Product Name:Cosentyx IV & SC	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

Notes	** For review process only: Refer to the table in the Background section for carrier-specific formulary products

Product Name:Cosentyx IV & SC	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)

- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name:Cosentyx IV & SC	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

Product Name:Cosentyx IV & SC	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name:Cosentyx SC	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

1 - Diagnosis of active enthesitis-related arthritis

AND

2 - Patient is 4 years of age or older

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

Product Name:Cosentyx SC	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 6]:

- Reduction in the total active (swollen and tender) joint count from baseline

- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Cosentyx SC	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

AND

2 - Prescribed by or in consultation with a dermatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one oral antibiotic (e.g., clindamycin, rifampin, tetracycline) [7]

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name:Cosentyx SC	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 7]:

- Reduction in the abscess and inflammatory nodule count from baseline
- Reduced formation of new sinus tracts and scarring
- Improvement in symptoms (e.g., pain, suppuration) from baseline

2 . References

1. Cosentyx prescribing information. Novartis Pharmaceuticals Corp. East Hanover, NJ. October 2023.

2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
6. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Care Res. 2019;71(6):717-734.
7. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: a publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019;81(1):91-101.

3 . Revision History

Date	Notes
12/20/2024	New Program

Cotellic (cobimetinib)

Prior Authorization Guideline

Guideline ID	GL-228824
Guideline Name	Cotellic (cobimetinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cotellic (cobimetinib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. **Histiocytic Neoplasms** Indicated as a single agent for the treatment of adult patients with histiocytic neoplasms.

2 . Criteria

Product Name:Cotellic	
Diagnosis	Melanoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COTELLIC	COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)	21533530200320	Brand

Approval Criteria

1 - Diagnosis of unresectable or metastatic melanoma

AND

2 - One of the following: [A]

2.1 Patient has a BRAF V600E mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

2.2 Patient has a BRAF V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Used in combination with Zelboraf (vemurafenib)*

Notes	*This product may require prior authorization.

Product Name:Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COTELLIC	COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)	21533530200320	Brand

Approval Criteria

1 - Diagnosis of histiocytic neoplasm

AND

2 - Used as monotherapy

Product Name:Cotellic	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COTELLIC	COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)	21533530200320	Brand

Approval Criteria

1 - Patient has not experienced disease progression while on therapy

3 . Endnotes

A. The cobas 4800 BRAF V600 Mutation Test is an FDA approved option and was used in the pivotal trial. [2, 3] The cobas 4800 BRAF V600 Mutation Test is also listed as the FDA approved companion diagnostic device for Zelboraf (vemurafenib). [3]

4 . References

1. Cotellic Prescribing Information. Genentech USA, Inc. South San Francisco, CA. May 2023.
2. Larkin J, Ascierto PA, Dréno B, et al. Combined vemurafenib and cobimetinib in BRAF-mutated melanoma. N Engl J Med. 2014;371(20):1867-76.
3. U.S. Food and Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm. Accessed May 23, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229117
Guideline Name	Coverage of Off-Label Non-FDA Approved Indications
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/2/2007
P&T Revision Date:	11/21/2024

1 . Criteria

Product Name:A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication	
Diagnosis	Off-label non-cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Off-label use			
Non-FDA approved use			

non-fda			
off-label			
off			

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [1]

OR

1.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [1]

OR

1.3 The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

Product Name:A drug or biological in an anti-cancer chemotherapeutic regimen	
Diagnosis	Off-label cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Off-label use			
Non-FDA approved use			

non-fda			
off-label			
off			

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in AHFS DI [2]

OR

1.2 Diagnosis is supported as a use in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, A]

OR

1.3 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, B]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood

- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

OR

1.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

2 . Background

Clinical Practice Guidelines

DRUGDEX Strength of Recommendation [6]

Class	Recommendation	Description

Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
Class Indeterminate	Evidence Inconclusive	

NCCN Categories of Evidence and Consensus [A]

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consens the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.
Against proposed off-label use	The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent

	of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use.

Level of Evidence Scale for Oncology Off-Label Use

A	**Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.**
B	**Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.**
C	**Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.**
G	**Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.**

3 . Endnotes

A. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

B. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use

randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed September 20, 2023.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed September 20, 2023.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed September 20, 2023.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-00443O. Available at: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=31#decision. Accessed September 20, 2023.
5. Wolters Kluwer Clinical Drug Information's Request for CMS evaluation of Lexi-Drugs as a compendium for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens. Available at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/covdoc31.pdf. Accessed September 20, 2023.
6. Micromedex Healthcare Series. Recommendation, Evidence, and Efficacy Ratings. https://www.micromedexsolutions.com/micromedex2/librarian/CS/8F8397/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/136D2F/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=3198&contentSetId=50&title=Recommendation%2C+Evidence+and+Efficacy+Ratings&servicesTitle=Recommendation%2C+Evidence+and+Efficacy+Ratings. Accessed September 20, 2023.

5 . Revision History

Date	Notes

1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-233262
Guideline Name	Crinone Gel 8% Quantity Limit
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	9/18/2024
P&T Revision Date:	

Note:

This quantity limit program is for the 8% strength of Crinone only. Requests for Crinone 4% should be reviewed using the General Quantity Limit Guideline.

1 . Indications

Drug Name: Crinone Gel 8%
Assisted Reproductive Technology Indicated for progesterone supplementation or replacement as part of an Assisted Reproductive Technology (“ART”) treatment for infertile women with progesterone deficiency. **Secondary Amenorrhea** Indicated for the treatment of secondary amenorrhea. Crinone 8% is indicated for use in women who have failed to respond to treatment with Crinone 4%.

2 . Criteria

Product Name:Crinone 8%	
Diagnosis	Assisted Reproductive Technology (ART)
Approval Length	12 Week(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
CRINONE	PROGESTERONE VAGINAL GEL 8%	55370060004020	Brand

Approval Criteria

1 - Quantity requested is intended for use as part of an Assisted Reproductive Technology (ART) treatment for infertile women

AND

2 - One of the following:

2.1 Dose or quantity requested is supported in the dosage and administration section of the manufacturer's prescribing information

OR

2.2 Dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

AND

3 - Trial and failure, contraindication, or intolerance to Endometrin

AND

4 - Prescribed by or in consultation with a reproductive endocrinologist

3 . References

1. Crinone Prescribing Information. Allergan USA, Inc. Irvine, CA. June 2017.
2. Endometrin Prescribing Information. Ferring Pharmaceuticals, Inc. Parsippany, NJ. January 2018.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-233326
Guideline Name	Crysvita (burosumab-twza)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/18/2025
P&T Approval Date:	
P&T Revision Date:	8/15/2024

1 . Indications

Drug Name: Crysvita (burosumab-twza)
X-Linked Hypophosphatemia (XLH) Indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older. **Tumor-Induced Osteomalacia** Indicated for the treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.

2 . Criteria

Product Name:Crysvita	
Diagnosis	X-Linked Hypophosphatemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CRYSVITA	BUROSUMAB-TWZA INJ 10 MG/ML	30909510602010	Brand
CRYSVITA	BUROSUMAB-TWZA INJ 20 MG/ML	30909510602020	Brand
CRYSVITA	BUROSUMAB-TWZA INJ 30 MG/ML	30909510602030	Brand

Approval Criteria

1 - Diagnosis of X-linked hypophosphatemia

AND

2 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Specialist experienced in the treatment of inborn errors of metabolism

AND

3 - One of the following:

3.1 Patient is 6 months to 17 years of age

OR

3.2 Both of the following:

3.2.1 Patient is 18 years of age or older

AND

3.2.2 Patient is a candidate for pharmacologic therapy by meeting one of the following: [2]

- Spontaneous insufficiency fractures
- Pending orthopedic procedures (e.g., joint replacement)
- Biochemical evidence of osteomalacia (i.e., elevated serum alkaline phosphatase)
- Disabling skeletal pain

AND

4 - Trial and failure, contraindication, or intolerance to conventional treatment with both of the following: [2, 3]

- Phosphate supplementation
- Vitamin D analog-based therapy (e.g, calcitriol, paricalcitol, doxercalciferol)

Product Name:Crysvita	
Diagnosis	X-Linked Hypophosphatemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CRYSVITA	BUROSUMAB-TWZA INJ 10 MG/ML	30909510602010	Brand
CRYSVITA	BUROSUMAB-TWZA INJ 20 MG/ML	30909510602020	Brand
CRYSVITA	BUROSUMAB-TWZA INJ 30 MG/ML	30909510602030	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in rickets, improvement in serum phosphorus or Radiographic Global Impression of Change [RGI-C] scores)

Product Name:Crysvita	
Diagnosis	Tumor-Induced Osteomalacia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CRYSVITA	BUROSUMAB-TWZA INJ 10 MG/ML	30909510602010	Brand
CRYSVITA	BUROSUMAB-TWZA INJ 20 MG/ML	30909510602020	Brand
CRYSVITA	BUROSUMAB-TWZA INJ 30 MG/ML	30909510602030	Brand

Approval Criteria

1 - Diagnosis of FGF23-related hypophosphatemia in Tumor-Induced Osteomalacia (TIO)

AND

2 - Tumor could not be curatively resected or localized

AND

3 - Patient is 2 years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to conventional treatment with both of the following: [4, 5]

- Phosphate supplementation
- Vitamin D analog-based therapy (e.g., calcitriol, paricalcitol, doxercalciferol)

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Endocrinologist

Product Name:Crysvita	
Diagnosis	Tumor-Induced Osteomalacia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CRYSVITA	BUROSUMAB-TWZA INJ 10 MG/ML	30909510602010	Brand
CRYSVITA	BUROSUMAB-TWZA INJ 20 MG/ML	30909510602020	Brand
CRYSVITA	BUROSUMAB-TWZA INJ 30 MG/ML	30909510602030	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increase in serum phosphorus level, improvement in osteoid thickness, osteoid surface, osteoid volume, mineralization lag time, or improvement as indicated by bone biopsy)

3 . References

1. Crysvita Prescribing Information. Ultragenyx Pharmaceutical Inc. Novato, CA. June 2020.
2. Carpenter TO, Imel EA, Holm IA, et al. A Clinician's guide to x-linked hypophosphatemia. J Bone Miner Res. 2011;26(7):1381-1388. doi:10.1002/jbmr.340.
3. Linglart A, Biosse-Duplan M, Briot K, et al. Therapeutic management of hypophosphatemic rickets from infancy to adulthood. Endocr Connect. 2014;3(1):R13-R30. doi:10.1530/EC-13-0103.
4. Chong W, Molinolo A, Chen C, Collins M. Tumor-induced osteomalacia. Endocr Relat Cancer. 2011;18(3):R53-R77.
5. Athonvarangkul D, Insogna K. New Therapies for Hypophosphatemia-Related to FGF23 Excess. Calcif Tissue Int. 2020.
6. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Feb 29 – Identifier NCT02304367, Study of KRN23 in Adult Subjects With Tumor-Induced Osteomalacia (TIO) or Epidermal Nevus Syndrome (ENS); December 1, 2014 [cited 2020 Jun 26]. Available from https://clinicaltrials.gov/ct2/show/NCT02304367.

7. Imanishi Y, Ito N, Rhee Y et al. Interim Analysis of a Phase 2 Open-Label Trial Assessing Burosumab Efficacy and Safety in Patients with Tumor-Induced Osteomalacia. J Bone Miner Res. 2020; 36(2):262-270.
8. Jan de Beur SM, Miller PD, Weber TJ, et al. Burosumab for the Treatment of Tumor-Induced Osteomalacia. J Bone Miner Res. 2021;36(4):627-635.

4 . Revision History

Date	Notes
2/18/2025	Quartz commercial copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-228830
Guideline Name	Daliresp (roflumilast)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Daliresp (roflumilast)
Chronic obstructive pulmonary disorder (COPD) Indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Limitations of Use: Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm. Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

2 . Criteria

Product Name:Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DALIRESP	ROFLUMILAST TAB 500 MCG	44450065000320	Brand
DALIRESP	ROFLUMILAST TAB 250 MCG	44450065000310	Brand
ROFLUMILAST	ROFLUMILAST TAB 250 MCG	44450065000310	Generic
ROFLUMILAST	ROFLUMILAST TAB 500 MCG	44450065000320	Generic

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD) [A, B]

AND

2 - History of COPD exacerbations which require the use of systemic corticosteroids, antibiotics, or hospital admission [C]

AND

3 - Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g., Combivent, Spiriva)

AND

4 - Trial and failure or intolerance to generic roflumilast (Applies to brand Daliresp only)

Notes	Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

Product Name:Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DALIRESP	ROFLUMILAST TAB 500 MCG	44450065000320	Brand
ROFLUMILAST	ROFLUMILAST TAB 250 MCG	44450065000310	Generic
ROFLUMILAST	ROFLUMILAST TAB 500 MCG	44450065000320	Generic
DALIRESP	ROFLUMILAST TAB 250 MCG	44450065000310	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and failure or intolerance to generic roflumilast (Applies to brand Daliresp only)

Notes	Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

3 . Endnotes

A. Patients enrolled in the pivotal trials had a forced expiratory volume in 1 second [FEV1] less than or equal to 50% of predicted and FEV1/forced vital capacity [FVC] less than 0.7). [1-3]
B. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) treatment guidelines, moderate COPD is defined as FEV1 less than 80% but greater than or equal to 50%; severe COPD is defined as FEV1 less than 50% but greater than or equal to 30%; and very severe COPD is defined as FEV1 less than 30%. [4]
C. In the pivotal studies the rate of moderate exacerbations was defined as requiring intervention with systemic glucocorticosteroids. Severe exacerbations were defined as leading to hospitalization and/or to death. [1]

4 . References

1. Daliresp Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. March 2020.
2. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): IBM Corporation.; Updated periodically. Available by subscription at: https://www.micromedexsolutions.com/. Accessed August 24, 2021.

3. FDA Summary Review. Accessed at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022522Orig1s000SumR.pdf. Accessed August 24, 2021.
4. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2023 report). Accessed at: file:///C:/Users/hfatani/Downloads/GOLD-2023-ver-1.3-17Feb2023_WMV.pdf. Accessed August 7, 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228827
Guideline Name	Daraprim (pyrimethamine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Daraprim (pyrimethamine)
Treatment of toxoplasmosis Indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

2 . Criteria

Product Name:Brand Daraprim, generic pyrimethamine	
Diagnosis	Toxoplasmosis
Approval Length	12 Months [A, B]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

DARAPRIM	PYRIMETHAMINE TAB 25 MG	13000040000310	Brand
PYRIMETHAMINE	PYRIMETHAMINE TAB 25 MG	13000040000310	Generic

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Patient is using pyrimethamine for one of the following: [2, 3]

- Active treatment of toxoplasmosis (e.g., toxoplasmic encephalitis, ocular toxoplasmosis)
- Secondary prophylaxis of toxoplasmosis
- Treatment of congenital toxoplasmosis

OR

1.1.2 All of the following: [2]

1.1.2.1 Patient is using pyrimethamine for primary prophylaxis of toxoplasmosis

AND

1.1.2.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.1.2.3 One of the following:

1.1.2.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.1.2.3.2 Evidence of life-threatening reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g., toxic epidermal necrolysis [TEN], Stevens-Johnson syndrome)

AND

1.2 Prescribed by or in consultation with an infectious disease specialist

Product Name:Brand Daraprim, generic pyrimethamine	
Diagnosis	Malaria (off-label)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARAPRIM	PYRIMETHAMINE TAB 25 MG	13000040000310	Brand
PYRIMETHAMINE	PYRIMETHAMINE TAB 25 MG	13000040000310	Generic

Approval Criteria

1 - Requests for coverage of any pyrimethamine products for the treatment and/or prophylaxis of malaria are not authorized and will not be approved. The use of pyrimethamine for the treatment and/or prophylaxis of malaria is not recommended by the Centers for Disease Control and Prevention (CDC) [5]

3 . Endnotes

A. Prescriber should consider discontinuation of primary prophylaxis if CD4 is greater than 200 cells/mm3 for more than 3 months after institution of combination antiretroviral therapy. [2]
B. Prescriber should consider discontinuation of secondary prophylaxis if CD4 is greater than 200 cells/mm3 for more than 6 months after institution of combination antiretroviral therapy. [2]

4 . References

1. Daraprim Prescribing Information. Vyera Pharmaceuticals. New York, NY. August 2017.
2. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/treatment-hiv-associated. Accessed May 27, 2024.

3. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/pediatric-oi/tables-pediatric-oi.pdf. Accessed May 27, 2024.
4. Parasites - Toxoplasmosis (Toxoplasma infection). https://www.cdc.gov/parasites/toxoplasmosis/health_professionals/index.html#tx. Accessed May 5, 2023.
5. Centers for Disease Control and Prevention. CDC Yellow Book 2024: Health Information for International Travel. New York: Oxford University Press; 2024. https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/malaria. Accessed May 27, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228829
Guideline Name	Darzalex (daratumumab), Darzalex Faspro (daratumumab and hyaluronidase-fihj) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Darzalex (daratumumab)
Multiple Myeloma - Monotherapy Indicated as monotherapy, for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. **Multiple Myeloma - Combination therapy** Indicated in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. **Multiple Myeloma - Combination therapy** Indicated in combination with carfilzomib and dexamethasone in adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. **Multiple Myeloma - Combination therapy** Indicated in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, melphalan, and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, thalidomide, and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.

Drug Name: Darzalex Faspro (daratumumab and hyaluronidase-fihj)

Multiple Myeloma - Monotherapy Indicated as monotherapy, for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

Multiple Myeloma - Combination Indicated in combination with lenalidomide and dexamethasone or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

Multiple Myeloma - Combination Indicated in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor.

Multiple Myeloma - Combination Indicated in combination with carfilzomib and dexamethasone in adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.

Newly Diagnosed Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, thalidomide, and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant.

Light Chain (AL) Amyloidosis Indicated in combination with bortezomib, cyclophosphamide, and dexamethasone for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis. This indication is approved under accelerated approval based on response rate.

Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Limitations of Use: DARZALEX FASPRO is not indicated and is not recommended for the treatment of patients with light chain (AL) amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.

2 . Criteria

Product Name:Darzalex	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX	DARATUMUMAB IV SOLN 100 MG/5ML	21354027002020	Brand
DARZALEX	DARATUMUMAB IV SOLN 400 MG/20ML	21354027002030	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name:Darzalex	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX	DARATUMUMAB IV SOLN 100 MG/5ML	21354027002020	Brand
DARZALEX	DARATUMUMAB IV SOLN 400 MG/20ML	21354027002030	Brand

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Used in combination with both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

Product Name:Darzalex Faspro	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name:Darzalex Faspro	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of multiple myeloma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name:Darzalex Faspro	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Used in combination with both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 One of the following:

2.2.2.1 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

OR

2.2.2.2 Used in combination with all of the following: (2)

- bortezomib
- lenalidomide
- dexamethasone

Product Name:Darzalex Faspro	
Diagnosis	Newly Diagnosed Multiple Myeloma

Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming newly diagnosed multiple myeloma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Used in combination with both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 One of the following:

2.2.2.1 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

OR

2.2.2.2 Used in combination with all of the following: (2)

- bortezomib
- lenalidomide
- dexamethasone

Product Name:Darzalex Faspro	
Diagnosis	Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Newly diagnosed light chain (AL) amyloidosis

AND

2 - Used in combination with ALL of the following:

- Bortezomib
- Cyclophosphamide
- Dexamethasone

AND

3 - All of the following: [3]

- Patient does not have New York Heart Association (NYHA) Class IIIB disease
- Patient does not have New York Heart Association (NYHA) Class IV disease
- Patient does not have Mayo Stage IIIB disease

Product Name:Darzalex Faspro	
Diagnosis	Light Chain Amyloidosis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming newly diagnosed light chain (AL) amyloidosis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with ALL of the following:

- Bortezomib
- Cyclophosphamide
- Dexamethasone

AND

3 - All of the following: [3]

- Patient does not have New York Heart Association (NYHA) Class IIIB disease
- Patient does not have New York Heart Association (NYHA) Class IV disease
- Patient does not have Mayo Stage IIIB disease

Product Name:Darzalex, Darzalex Faspro	
Diagnosis	All Indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand
DARZALEX	DARATUMUMAB IV SOLN 100 MG/5ML	21354027002020	Brand
DARZALEX	DARATUMUMAB IV SOLN 400 MG/20ML	21354027002030	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Darzalex Prescribing Information. Janssen Biotech, Inc. Horsham, PA. January 2023.

2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Multiple Myeloma v4.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August 13, 2024
3. Darzalex Faspro Prescribing Information. Janssen Biotech, Inc. Horsham, PA. July 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Daurismo (glasdegib)

Prior Authorization Guideline

Guideline ID	GL-228396
Guideline Name	Daurismo (glasdegib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Daurismo (glasdegib)
Acute Myeloid Leukemia (AML) Indicated for use in combination with low-dose cytarabine, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adult patients who are greater than or equal to 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.

2 . Criteria

Product Name:Daurismo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DAURISMO	GLASDEGIB MALEATE TAB 25 MG (BASE EQUIVALENT)	21370030300320	Brand
DAURISMO	GLASDEGIB MALEATE TAB 100 MG (BASE EQUIVALENT)	21370030300335	Brand

Approval Criteria

1 - Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

AND

2 - Used in combination with low-dose cytarabine

AND

3 - One of the following:

3.1 Patient is greater than or equal to 75 years old

OR

3.2 Patient has comorbidities that preclude use of intensive induction chemotherapy [A]

Product Name:Daurismo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DAURISMO	GLASDEGIB MALEATE TAB 25 MG (BASE EQUIVALENT)	21370030300320	Brand
DAURISMO	GLASDEGIB MALEATE TAB 100 MG (BASE EQUIVALENT)	21370030300335	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Examples of comorbid conditions are severe cardiac disease, ECOG performance status greater than or equal to 2, or baseline creatinine greater than 1.3 mg/dL. [2]

4 . References

1. Daurismo Prescribing Information. Pfizer Inc. New York, NY. March 2023.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. v.6.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed February 7, 2024.

Prior Authorization Guideline

Guideline ID	GL-228636
Guideline Name	Daybue (trofinetide) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Daybue (trofinetide)
Rett Syndrome Indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.

2 . Criteria

Product Name:Daybue	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DAYBUE	TROFINETIDE ORAL SOLN 200 MG/ML	74653075002020	Brand

Approval Criteria

1 - Diagnosis of Rett syndrome

AND

2 - One of the following:

2.1 Presence of ALL of the following clinical signs and symptoms: [3-8]

- A pattern of development, regression, then recovery or stabilization
- Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose
- Partial or complete loss of spoken language
- Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing
- Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait

OR

2.2 Molecular genetic testing confirms mutations in the MECP2 gene

AND

3 - Patient is 2 years of age or older

AND

4 - Prescribed by or in consultation with one of the following: [A, 2]

- Geneticist

- Neurologist

Product Name:Daybue	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DAYBUE	TROFINETIDE ORAL SOLN 200 MG/ML	74653075002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Daybue	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DAYBUE	TROFINETIDE ORAL SOLN 200 MG/ML	74653075002020	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Rett syndrome

AND

2 - Submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Presence of ALL of the following clinical signs and symptoms: [3-8]

- A pattern of development, regression, then recovery or stabilization

- Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose
- Partial or complete loss of spoken language
- Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing
- Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait

OR

2.2 Molecular genetic testing confirms mutations in the MECP2 gene

AND

3 - Patient is 2 years of age or older

AND

4 - Prescribed by or in consultation with one of the following: [A, 2]

- Geneticist
- Neurologist

3 . Endnotes

A. A neurologist, or geneticist should be consulted to confirm the diagnosis of Rett syndrome. [9]

4 . References

1. Daybue Prescribing Information. Acadia Pharmaceuticals Inc. San Diego, CA March 2023.
2. National Institute of Neurological Disorders and Stroke. Rett Syndrome. Available at: https://www.ninds.nih.gov/health-information/disorders/rett-syndrome. Accessed April 3, 2023.
3. Clinicaltrials.gov. Study of Trofinetide for the Treatment of Girls and Women With Rett Syndrome (LAVENDER™). Available at:

https://clinicaltrials.gov/ct2/results?cond=&term=NCT04181723&cntry=&state=&city=&dist=. Accessed April 3, 2023.
4. Eunice Kennedy Shriver National Institute of Child Health and Human Development. Rett syndrome. Available at: https://www.nichd.nih.gov/health/topics/rett/conditioninfo/diagnosed. Accessed April 3, 2023.
5. Rett syndrome. Available at: https://raisingchildren.net.au/disability/guide-to-disabilities/assessment-diagnosis/rett-syndrome. Accessed April 3, 2023.
6. International Rett Syndrome Foundation. Available at: https://www.rettsyndrome.org/about-rett-syndrome/rett-syndrome-diagnosis/. Accessed April 3, 2023.
7. Neul, J., Kaufmann, W., et al. Rett Syndrome:Revised Diagnostic Criteria and Nomenclature. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058521/. Accessed April 7, 2023.
8. Clinical consult with pediatric neurologist. April 17, 2023.
9. Optum May P & T

Prior Authorization Guideline

Guideline ID	GL-228832
Guideline Name	Deferasirox products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Exjade (deferasirox), deferasirox tablet, Jadenu (deferasirox), Jadenu Sprinkle (deferasirox)
Chronic Iron Overload Due to Blood Transfusions (Transfusional Iron Overload) Indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. Limitations of Use: The safety and efficacy of deferasirox when administered with other iron chelation therapy have not been established. **Treatment of Chronic Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes** Indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L. Limitations of Use: The safety and efficacy of deferasirox when administered with other iron chelation therapy have not been established. **Off Label Uses: Myelodysplastic syndrome (MDS)** Low to intermediate risk myelodysplastic syndrome (MDS) for management of iron overload and in potential transplant patients who have received more than 20 red blood cell transfusions [11]

2 . Criteria

Product Name:Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JADENU	DEFERASIROX TAB 90 MG	93100025000320	Brand
JADENU	DEFERASIROX TAB 180 MG	93100025000330	Brand
JADENU	DEFERASIROX TAB 360 MG	93100025000340	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Brand

Approval Criteria

1 - Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has a baseline ferritin level more than 1,000 mcg/L

AND

4 - Patient has required the transfusion of at least 100 mL/kg packed red blood cells

AND

5 - Trial and failure of generic deferasirox

Product Name:Generic deferasirox	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Generic
DEFERASIROX	DEFERASIROX TAB 90 MG	93100025000320	Generic
DEFERASIROX	DEFERASIROX TAB 360 MG	93100025000340	Generic
DEFERASIROX	DEFERASIROX TAB 180 MG	93100025000330	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Generic

Approval Criteria

1 - Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has a baseline ferritin level more than 1,000 mcg/L

AND

4 - Patient has required the transfusion of at least 100 mL/kg packed red blood cells

Product Name:Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JADENU	DEFERASIROX TAB 90 MG	93100025000320	Brand
JADENU	DEFERASIROX TAB 180 MG	93100025000330	Brand
JADENU	DEFERASIROX TAB 360 MG	93100025000340	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Brand

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient has Low or Intermediate-1 disease or is a potential transplant patient

AND

3 - Patient has received more than 20 red blood cell transfusions

AND

4 - Trial and failure of generic deferasirox

Product Name:Generic deferasirox	
Diagnosis	Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Generic
DEFERASIROX	DEFERASIROX TAB 90 MG	93100025000320	Generic
DEFERASIROX	DEFERASIROX TAB 360 MG	93100025000340	Generic
DEFERASIROX	DEFERASIROX TAB 180 MG	93100025000330	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Generic

DEFERASIROX	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Generic

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient has Low or Intermediate-1 disease or is a potential transplant patient

AND

3 - Patient has received more than 20 red blood cell transfusions

Product Name:Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis) & Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JADENU	DEFERASIROX TAB 90 MG	93100025000320	Brand
JADENU	DEFERASIROX TAB 180 MG	93100025000330	Brand
JADENU	DEFERASIROX TAB 360 MG	93100025000340	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Brand

Approval Criteria

1 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

AND

2 - Trial and failure of generic deferasirox

Product Name:Generic deferasirox	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis) & Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Generic
DEFERASIROX	DEFERASIROX TAB 90 MG	93100025000320	Generic
DEFERASIROX	DEFERASIROX TAB 360 MG	93100025000340	Generic
DEFERASIROX	DEFERASIROX TAB 180 MG	93100025000330	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Generic

Approval Criteria

1 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

Product Name:Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JADENU	DEFERASIROX TAB 90 MG	93100025000320	Brand
JADENU	DEFERASIROX TAB 180 MG	93100025000330	Brand
JADENU	DEFERASIROX TAB 360 MG	93100025000340	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Brand

Approval Criteria

1 - Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

AND

2 - Patient is 10 years of age or older

AND

3 - Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher

AND

4 - Serum ferritin level greater than 300 mcg/L

AND

5 - Trial and failure of generic deferasirox

Product Name:Generic deferasirox	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Generic
DEFERASIROX	DEFERASIROX TAB 90 MG	93100025000320	Generic
DEFERASIROX	DEFERASIROX TAB 360 MG	93100025000340	Generic
DEFERASIROX	DEFERASIROX TAB 180 MG	93100025000330	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Generic

Approval Criteria

1 - Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

AND

2 - Patient is 10 years of age or older

AND

3 - Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher

AND

4 - Serum ferritin level greater than 300 mcg/L

Product Name:Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JADENU	DEFERASIROX TAB 90 MG	93100025000320	Brand
JADENU	DEFERASIROX TAB 180 MG	93100025000330	Brand
JADENU	DEFERASIROX TAB 360 MG	93100025000340	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Brand

Approval Criteria

1 - Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher

AND

2 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

AND

3 - Trial and failure of generic deferasirox

Product Name:Generic deferasirox	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Generic
DEFERASIROX	DEFERASIROX TAB 90 MG	93100025000320	Generic
DEFERASIROX	DEFERASIROX TAB 360 MG	93100025000340	Generic
DEFERASIROX	DEFERASIROX TAB 180 MG	93100025000330	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Generic

Approval Criteria

1 - Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher

AND

2 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

3 . References

1. Exjade Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2020.
2. Cappellini MD, Cohen A, Piga A, et al. A Phase III study of deferasirox (ICL670), a once-daily oral iron chelator, in patients with [beta]-thalassemia. Blood. 2006;107(9):3455-62.
3. Cappellini MD. Iron-chelating therapy with the new oral agent ICL670 (Exjade). Best Pract Res Clin Haematol. 2005;18(2):289-98.
4. Galanello R, Piga A, Alberti D, Rouan MC, Bigler H, Sechaud R. Safety, tolerability, and pharmacokinetics of ICL670, a new orally active iron-chelating agent in patients with transfusion-dependent iron overload due to beta-thalassemia. J Clin Pharmacol. 2003;43(6):565-72.
5. Nisbet-Brown E, Olivieri NF, Giardina PJ, et al. Effectiveness and safety of ICL670 in iron-loaded patients with thalassaemia: a randomized, double-blind, placebo-controlled, dose-escalation trial. Lancet. 2003;361(9369):1597-602.
6. International Association of Sickle Cell Nurses and Physician Assistants. Nursing Practice Guidelines: Care of the Patient with Sickle Cell Disease and Iron Overload. 2008. http://www.iascnapa.org/guidelines/Guidelines_IronOverload.pdf. Accessed on April 8, 2021.
7. Ho PJ, Tay L, Linderman R, Catley L, Bowden DK. Australian guidelines for the assessment of iron overload and iron chelation in transfusion-dependent thalassaemia major, sickle cell disease and other congenital anaemias. Intern Med J. 2011;41(7):516-24.
8. Angelucci E, Barosi G, Camaschella C, et al. Italian Society of Hematology practice guidelines for the management of iron overload in thalassemia major and related disorders. Haematologica. 2008;93(5):741-52.
9. Porter JB and Shah FT. Iron overload in thalassemia and related conditions: therapeutic goals and assessment of response to chelation therapies. 2010 Dec;24(6):1109-30.
10. Jadenu, Jadenu Sprinkle Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. July 2020.
11. AHFS Drug Information (Adult and Pediatric) [Internet database]. Bethesda, Maryland. Lexicomp, Inc. Updated periodically. Available by subscription at: http://online.lexi.com/. Accessed on April 8, 2021.
12. Deferasirox tablet Prescribing Information. Cipla USA, Inc. Warren, NJ. August 2020.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228834
Guideline Name	Demser (metyrosine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Demser (metyrosine)
Pheochromocytoma Indicated for the treatment of patients with pheochromocytoma for preoperative preparation of patients for surgery, management of patients when surgery is contraindicated, and chronic treatment of patients with malignant pheochromocytoma. Metyrosine capsules are not recommended for the control of essential hypertension.

2 . Criteria

Product Name:Brand Demser, generic metyrosine	
Diagnosis	Preoperative preparation
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
METYROSINE	METYROSINE CAP 250 MG	36300025000110	Generic
DEMSER	METYROSINE CAP 250 MG	36300025000110	

Approval Criteria

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing:

- plasma free metanephrines
- urinary fractioned metanephrines

AND

2 - Medication is being used for preoperative preparation

AND

3 - Trial and failure, contraindication, or intolerance to both of the following:

- alpha-adrenergic blocker (e.g., phenoxybenzamine, doxazosin, terazosin)
- beta-adrenergic blocker (e.g., propranolol, metoprolol)

AND

4 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Endocrine surgeon

Product Name:Brand Demser, generic metyrosine	
Diagnosis	Treatment of pheochromocytoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
METYROSINE	METYROSINE CAP 250 MG	36300025000110	Generic
DEMSER	METYROSINE CAP 250 MG	36300025000110	

Approval Criteria

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing:

- plasma free metanephrines
- urinary fractioned metanephrines

AND

2 - Patient with hormonally active (catecholamine excess) pheochromocytoma

AND

3 - One of the following:

3.1 Patient is not a candidate for surgery

OR

3.2 Chronic treatment due to malignant pheochromocytoma

AND

4 - Patient has not reached normotension after treatment with a selective alpha-1-adrenergic blocker (e.g., doxazosin, terazosin) and beta-adrenergic blocker (e.g., propranolol, metoprolol)

AND

5 - Medication will not be used to control essential hypertension

AND

6 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Provider who specializes in the management of pheochromocytoma

Product Name:Brand Demser, generic metyrosine	
Diagnosis	Treatment of pheochromocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
METYROSINE	METYROSINE CAP 250 MG	36300025000110	Generic
DEMSER	METYROSINE CAP 250 MG	36300025000110	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decreased frequency and severity of hypertensive attacks)

3 . References

1. Metyrosine Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. November 2020.
2. Naruse M, Satoh F, Tanabe A, et al. Efficacy and safety of metyrosine in pheochromocytoma/paraganglioma: a multi-center trial in Japan. Endocrine Journal. 2018;65(3):359-371.
3. Lenders JWM, Duh Q-Y, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism. 2014;99(6):1915-1942.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228398
Guideline Name	Diabetic Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Riomet (metformin)
Type 2 diabetes mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.
Drug Name: Cycloset (bromocriptine)
Type 2 diabetes mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Cycloset should not be used to treat type 1 diabetes or diabetic ketoacidosis; 2) Limited efficacy data in combination with thiazolidinediones; 3) Efficacy has not been confirmed in combination with insulin.

2 . Criteria

Product Name:Cycloset, Brand Riomet

Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
CYCLOSET	BROMOCRIPTINE MESYLATE TAB 0.8 MG (BASE EQUIVALENT)	27574020100320	Brand
RIOMET	METFORMIN HCL ORAL SOLN 500 MG/5ML	27250050002020	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), intolerance, or contraindication to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

3 . References

1. Cycloset Prescribing Information. VeroScience, LLC. Tiverton, RI. August 2020.
2. Riomet Prescribing Information. Mikart, LLC. Atlanta, GA. December 2018.

Prior Authorization Guideline

Guideline ID	GL-241255
Guideline Name	Diabetic GLP-1 Agonists
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/21/2025

1 . Indications

Drug Name: Byetta (exenatide injection)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Byetta is not indicated for use in patients with type 1 diabetes, 2) Byetta contains exenatide and should not be used with other products containing the active ingredient exenatide. 3) Byetta has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
Drug Name: Bydureon BCise (exenatide extended-release)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus. Limitations of Use: 1) Bydureon BCise is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans, 2) Bydureon BCise is not indicated for use in patients with type 1 diabetes mellitus, 3) Bydureon BCise is an extended-release formulation of exenatide and should not be used with other products containing the

active ingredient exenatide, 4) Bydureon BCise has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
Drug Name: Mounjaro (tirzepatide)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Mounjaro has not been studied in patients with a history of pancreatitis. It is not indicated for use in patients with type 1 diabetes mellitus.
Drug Name: Trulicity (dulaglutide)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors. Limitations of Use: 1) Trulicity has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis, 2) should not be used in patients with type 1 diabetes mellitus, 3) has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and is therefore not recommended in these patients.
Drug Name: Victoza (liraglutide injection)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of Use: 1) Victoza should not be used in patients with type 1 diabetes mellitus, 2) contains liraglutide and should not be coadministered with other liraglutide-containing products.

2 . Criteria

Product Name:Byetta*,**,***, Bydureon BCise*,**,***, Mounjaro*,**,***, Trulicity*,**,***, Liraglutide*,**,***	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

TRULICITY	DULAGLUTIDE SOLN PEN-INJECTOR 0.75 MG/0.5ML	2717001500D520	Brand
TRULICITY	DULAGLUTIDE SOLN PEN-INJECTOR 1.5 MG/0.5ML	2717001500D530	Brand
BYDUREON BCISE	EXENATIDE EXTENDED RELEASE SUSP AUTO-INJECTOR 2 MG/0.85ML	2717002000D420	Brand
TRULICITY	DULAGLUTIDE SOLN PEN-INJECTOR 3 MG/0.5ML	2717001500D540	Brand
TRULICITY	DULAGLUTIDE SOLN PEN-INJECTOR 4.5 MG/0.5ML	2717001500D550	Brand
BYETTA	EXENATIDE SOLN PEN-INJECTOR 5 MCG/0.02ML	2717002000D220	Brand
BYETTA	EXENATIDE SOLN PEN-INJECTOR 10 MCG/0.04ML	2717002000D240	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 2.5 MG/0.5ML	2717308000D510	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 5 MG/0.5ML	2717308000D515	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 7.5 MG/0.5ML	2717308000D520	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 10 MG/0.5ML	2717308000D525	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 12.5 MG/0.5ML	2717308000D530	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 15 MG/0.5ML	2717308000D535	Brand
LIRAGLUTIDE	LIRAGLUTIDE SOLN PEN-INJECTOR 18 MG/3ML (6 MG/ML)	2717005000D220	Generic

Approval Criteria

1 - One of the following:

1.1 For patients requiring ongoing drug treatment for type 2 diabetes mellitus, submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

OR

1.2 Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by one of the following laboratory values:

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL) during OGTT (oral glucose tolerance test)
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

AND

2 - One of the following:

2.1 For Byetta, Mounjaro patient is 18 years of age or older

OR

2.2 For Bydureon Bcise, Trulicity, or liraglutide, patient is 10 years of age or older

AND

3 - Medication is not being co-administered with any of the following:

- GLP-1 receptor agonists (e.g., Victoza, Ozempic, Rybelsus, Trulicity, Wegovy)
- Tirzepatide-containing products (e.g., Mounjaro)

Notes	*If being used for any other indications, deny the case for medical nec essity and do not review for off-label use. **If patient meets criteria above, please approve at GPI-10. ***If being used for weight loss or obesity, deny as plan exclusion

Product Name:Byetta*,**, Bydureon BCise*,**, Mounjaro*,**, Trulicity*,**, Liraglutide*,**	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRULICITY	DULAGLUTIDE SOLN PEN-INJECTOR 0.75 MG/0.5ML	2717001500D520	Brand
TRULICITY	DULAGLUTIDE SOLN PEN-INJECTOR 1.5 MG/0.5ML	2717001500D530	Brand
BYDUREON BCISE	EXENATIDE EXTENDED RELEASE SUSP AUTO-INJECTOR 2 MG/0.85ML	2717002000D420	Brand
TRULICITY	DULAGLUTIDE SOLN PEN-INJECTOR 3 MG/0.5ML	2717001500D540	Brand

TRULICITY	DULAGLUTIDE SOLN PEN-INJECTOR 4.5 MG/0.5ML	2717001500D550	Brand
BYETTA	EXENATIDE SOLN PEN-INJECTOR 5 MCG/0.02ML	2717002000D220	Brand
BYETTA	EXENATIDE SOLN PEN-INJECTOR 10 MCG/0.04ML	2717002000D240	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 2.5 MG/0.5ML	2717308000D510	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 5 MG/0.5ML	2717308000D515	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 7.5 MG/0.5ML	2717308000D520	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 10 MG/0.5ML	2717308000D525	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 12.5 MG/0.5ML	2717308000D530	Brand
MOUNJARO	TIRZEPATIDE SOLN PEN-INJECTOR 15 MG/0.5ML	2717308000D535	Brand
LIRAGLUTIDE	LIRAGLUTIDE SOLN PEN-INJECTOR 18 MG/3ML (6 MG/ML)	2717005000D220	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Medication is not being co-administered with any of the following:

- GLP-1 receptor agonists (e.g., Victoza, Ozempic, Rybelsus, Trulicity, Wegovy)
- Tirzepatide-containing products (e.g., Mounjaro)

Notes	* If patient meets criteria above, please approve at GPI-10. **If being used for weight loss or obesity, deny as plan exclusion

3 . Endnotes

A. In people with CKD, established CVD or multiple risk factors for CVD, the decision to use a GLP-1 RA with proven benefit should be independent of background use of metformin. The GLP-1 RAs that have shown proven benefit include Ozempic, Trulicity, and Victoza [9].

4 . References

1. Byetta Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. December 2022.
2. Victoza Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. July 2023.
3. Trulicity Prescribing Information. Eli Lily and Company. Indianapolis, IN. December 2022.
4. Bydureon BCise Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. May 2023.
5. Ozempic Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. September 2023.
6. Mounjaro Prescribing Information. Eli Lilly and Company. Indianapolis, IN. July 2023.
7. Rybelsus Prescribing Information. Novo Nordisk A/S. Bagsvaerd, Denmark. January 2024.
8. American Diabetes Association (ADA) 2023 Standards of Care in Diabetes to Guide Prevention, Diagnosis, and Treatment for People Living with Diabetes. Accessed May 18, 2023.

5 . Revision History

Date	Notes
4/21/2025	Note updated

Prior Authorization Guideline

Guideline ID	GL-228840
Guideline Name	Diacomit (stiripentol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Diacomit (stiripentol)
Dravet syndrome (DS) Indicated for the treatment of seizures associated with Dravet syndrome in patients taking clobazam who are 6 months of age or older and weighing 7 kg or more.There are no clinical data to support the use of DIACOMIT as monotherapy in Dravet syndrome.

2 . Criteria

Product Name:Diacomit	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIACOMIT	STIRIPENTOL CAP 250 MG	72600070000120	Brand
DIACOMIT	STIRIPENTOL CAP 500 MG	72600070000130	Brand
DIACOMIT	STIRIPENTOL PACKET 250 MG	72600070003020	Brand
DIACOMIT	STIRIPENTOL PACKET 500 MG	72600070003030	Brand

Approval Criteria

1 - Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2 - Used in combination with clobazam

AND

3 - BOTH of the following:

- Patient is 6 months of age or older
- Patient weighs 7kg or more

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Diacomit	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIACOMIT	STIRIPENTOL CAP 250 MG	72600070000120	Brand

DIACOMIT	STIRIPENTOL CAP 500 MG	72600070000130	Brand
DIACOMIT	STIRIPENTOL PACKET 250 MG	72600070003020	Brand
DIACOMIT	STIRIPENTOL PACKET 500 MG	72600070003030	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Used in combination with clobazam

3 . References

1. Diacomit Prescribing Information. Biocodex. Gentilly, France. July 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Dibenzyline (phenoxybenzamine)

Prior Authorization Guideline

Guideline ID	GL-228837
Guideline Name	Dibenzyline (phenoxybenzamine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Dibenzyline (phenoxybenzamine)
Pheochromocytoma Indicated in the treatment of pheochromocytoma to control episodes of hypertension and swelling.

2 . Criteria

Product Name:Brand Dibenzyline, generic phenoxybenzamine	
Diagnosis	Pheochromocytoma
Approval Length	1 Time(s) [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

PHENOXYBENZAMINE HYDROCHLORIDE	PHENOXYBENZAMINE HCL CAP 10 MG	36300010100105	Generic
DIBENZYLINE	PHENOXYBENZAMINE HCL CAP 10 MG	36300010100105	Brand

Approval Criteria

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: [2]

- plasma free metanephrines
- urinary fractioned metanephrines

AND

2 - Medication is being used for preoperative preparation [A,1]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following:

- doxazosin
- terazosin
- prazosin

AND

4 - Treatment will also include a high-sodium diet and fluid intake [B]

AND

5 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Endocrine surgeon

3 . Endnotes

A. Phenoxybenzamine is most commonly used for preoperative control of blood pressure. Its only current clinical use is in preparing patients with pheochromocytoma for surgery. [1]
B. Retrospective studies report that initiation of high-sodium diet a few days after the start of alpha-adrenergic receptor blockade reverses blood volume contraction, prevents orthostatic hypotension before surgery, and reduces the risk of significant hypotension after surgery. [2]

4 . References

1. Farrugia F, Martikos G, Tzanetis P, et al. Pheochromocytoma, diagnosis and treatment: Review of the literature. Endocrine Regulations. 2017;51(3):168-181.
2. Lenders JWM, Duh Q-Y, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism. 2014;99(6):1915-1942.
3. Phenoxybenzamine Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. July 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233231
Guideline Name	Dichlorphenamide Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/18/2015
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Keveyis (dichlorphenamide)
Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants Indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.
Drug Name: Ormalvi (dichlorphenamide)
Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants Indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

2 . Criteria

Product Name:Brand Keveyis, Brand Ormalvi, Generic dichlorphenamide	
Approval Length	3 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KEVEYIS	DICHLORPHENAMIDE TAB 50 MG	37100020000305	Brand
DICHLORPHENAMIDE	DICHLORPHENAMIDE TAB 50 MG	37100020000305	Generic
ORMALVI	DICHLORPHENAMIDE TAB 50 MG	37100020000305	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Primary hyperkalemic periodic paralysis
- Primary hypokalemic periodic paralysis
- Paramyotonia Congenita with periodic paralysis [2]
- Andersen-Tawil syndrome [3]

AND

2 - One of the following [3]:

2.1 Patient has positive genetic panel for periodic paralysis

OR

2.2 One of the following tests demonstrated positive results for periodic paralysis:

- EMG/nerve conduction studies
- Long exercise test
- Muscle biopsy
- Muscle MRI

AND

3 - Patient has distinct, regular episodes of weakness at least once a week [4]

AND

4 - Trial and inadequate response, contraindication or intolerance to acetazolamide [off-label] [5]

AND

5 - Provider attests that other known causes of potassium fluctuations have been excluded (e.g., thyrotoxic periodic paralysis, drugs that cause potassium abnormalities, etc)

AND

6 - For Brand Keveyis and Brand Ormalvi, trial and failure or intolerance to generic dichlorphenamide

AND

7 - Prescribed by or in consultation with a neurologist

Product Name:Brand Keveyis, Brand Ormalvi, Generic dichlorphenamide	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KEVEYIS	DICHLORPHENAMIDE TAB 50 MG	37100020000305	Brand
DICHLORPHENAMIDE	DICHLORPHENAMIDE TAB 50 MG	37100020000305	Generic
ORMALVI	DICHLORPHENAMIDE TAB 50 MG	37100020000305	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by a decrease in weekly attack frequency from baseline [4]

AND

2 - For Brand Keveyis and Brand Ormalvi, trial and failure or intolerance to generic dichlorphenamide

3 . Endnotes

A. Prescribers should evaluate the patient's response to Keveyis after 2 months of treatment to decide whether treatment should be continued [1]. An additional month is added to the initial authorization duration to allow patient follow-up with the provider.

4 . References

1. Keveyis Prescribing Information. Stonebridge Biopharma; Trevose, PA. November 2019
2. Tawil R, McDermott MP, Brown R Jr, et al. Randomized trials of dichlorphenamide in the periodic paralyses. Working Group on Periodic Paralysis. Ann Neurol. 2000;47(1):46-53.
3. Ciafaloni E, Jackson C, Kincaid J, et al. Primary Periodic Paralysis: The Diagnostic Journey.; 2019. Accessed January 4, 2023. https://keveyis.com/wp-content/uploads/keveyis-ppp-diagnostic-journey.pdf
4. Sansone VA, Burge J, McDermott MP, et al. Randomized, placebo-controlled trials of dichlorphenamide in periodic paralysis. Neurology. 2016;86(15):1408-1416. doi:10.1212/wnl.0000000000002416
5. Statland JM, Fontaine B, Hanna MG, et al. Review of the Diagnosis and Treatment of Periodic Paralysis. Muscle & Nerve. 2017;57(4):522-530. doi:10.1002/mus.26009
6. Ormalvi Prescribing Information. CYCLE PHARMACEUTICALS LTD. Cambridge, United Kingdom. February 2024.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-233288
Guideline Name	Doptelet (avatrombopag)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	7/18/2018
P&T Revision Date:	6/19/2024

1 . Indications

Drug Name: Doptelet (avatrombopag)
Thrombocytopenia in Patients with Chronic Liver Disease (CLD) Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. **Thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP)** Indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

2 . Criteria

Product Name:Doptelet	
Diagnosis	Thrombocytopenia in Patients with Chronic Liver Disease (CLD)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DOPTELET	AVATROMBOPAG MALEATE TAB 20 MG (BASE EQUIV)	82405010200320	Brand

Approval Criteria

1 - Diagnosis of thrombocytopenia

AND

2 - Patient has chronic liver disease

AND

3 - Patient is scheduled to undergo a procedure

AND

4 - Baseline platelet count is less than 50,000/mcL [1, 5]

Product Name:Doptelet	
Diagnosis	Thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

DOPTELET	AVATROMBOPAG MALEATE TAB 20 MG (BASE EQUIV)	82405010200320	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Chronic immune (idiopathic) thrombocytopenic purpura (ITP)
- Relapsed/refractory ITP [3]

AND

2 - Baseline platelet count is less than 30,000/mcL [2-4]

AND

3 - Trial and failure, contraindication, or intolerance to at least ONE of the following: [1-4]

- Corticosteroids
- Immunoglobulins
- Splenectomy

AND

4 - Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding [3]

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Doptelet	
Diagnosis	Thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DOPTELET	AVATROMBOPAG MALEATE TAB 20 MG (BASE EQUIV)	82405010200320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding

3 . References

1. Doptelet Prescribing Information. AkaRx, Inc. Durham, NC. July 2021.
2. Neunert C, Terrell D, Arnold D, et al. The American Society of Hematology 2019 Evidence-based practice guideline for immune thrombocytopenia. Available at: https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for. Accessed January 3, 2024.
3. Per clinical consult with hematologist/oncologist. June 20, 2018.
4. Jurczak W, Chojnowski K, Mayer J, et al. Phase 3 randomised study of avatrombopag, a novel thrombopoietin receptor agonist for the treatment of chronic immune thrombocytopenia. Br J Haematol. 2018;183(3):479-490.
5. Terrault N, Chen YC, Izumi N, et al. Avatrombopag before procedures reduces need for platelet transfusion in patients with chronic liver disease and thrombocytopenia. Gastroenterology. 2018 Sep;155(3):705-718. doi: 10.1053/j.gastro.2018.05.025. Epub 2018 May 17.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-233264
Guideline Name	DPP-4 Inhibitors - ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/20/2007
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin extended-release), Zituvimet (sitagliptin/metformin), Zituvimet XR (sitagliptin/metformin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Should not be used in patients with type 1 diabetes mellitus, 2) Has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUMET.
Drug Name: Januvia (sitagliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Januvia should not be used in patients with type 1 diabetes, 2) Januvia has not been studied in patients with a history of

pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUVIA.
Drug Name: Onglyza (saxagliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis, as it would not be effective in these settings.
Drug Name: Tradjenta (linagliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Not recommended in patients with type 1 diabetes mellitus as it would not be effective., 2) Has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using TRADJENTA.
Drug Name: Jentadueto (linagliptin/metformin), Jentadueto XR (linagliptin/metformin extended-release)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Not recommended in patients with type 1 diabetes mellitus., 2) Has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using JENTADUETO.
Drug Name: Kazano (alogliptin/metformin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Not recommended for use in patients with type 1 diabetes mellitus.
Drug Name: Kombiglyze XR (saxagliptin/metformin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate. Limitations of use: Not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
Drug Name: Nesina (alogliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Not recommended for use in patients with type 1 diabetes.
Drug Name: Oseni (alogliptin/pioglitazone)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Should not be used in patients with type 1 diabetes mellitus.
Drug Name: Zituvio (sitagliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) not recommended in patients with type 1 diabetes mellitus, 2) has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using ZITUVIO.

2 . Criteria

Product Name:Januvia, Janumet, Janumet XR, Jentadueto, Jentadueto XR, Tradjenta	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
JANUMET	SITAGLIPTIN-METFORMIN HCL TAB 50-500 MG	27992502700320	Brand
JANUMET	SITAGLIPTIN-METFORMIN HCL TAB 50-1000 MG	27992502700340	Brand
JANUMET XR	SITAGLIPTIN-METFORMIN HCL TAB ER 24HR 50-500 MG	27992502707520	Brand
JANUMET XR	SITAGLIPTIN-METFORMIN HCL TAB ER 24HR 50-1000 MG	27992502707530	Brand
JANUMET XR	SITAGLIPTIN-METFORMIN HCL TAB ER 24HR 100-1000 MG	27992502707540	Brand
JANUVIA	SITAGLIPTIN PHOSPHATE TAB 25 MG (BASE EQUIV)	27550070100320	Brand
JANUVIA	SITAGLIPTIN PHOSPHATE TAB 50 MG (BASE EQUIV)	27550070100330	Brand
JANUVIA	SITAGLIPTIN PHOSPHATE TAB 100 MG (BASE EQUIV)	27550070100340	Brand
TRADJENTA	LINAGLIPTIN TAB 5 MG	27550050000320	Brand
JENTADUETO	LINAGLIPTIN-METFORMIN HCL TAB 2.5-500 MG	27992502400320	Brand
JENTADUETO	LINAGLIPTIN-METFORMIN HCL TAB 2.5-850 MG	27992502400330	Brand
JENTADUETO	LINAGLIPTIN-METFORMIN HCL TAB 2.5-1000 MG	27992502400340	Brand

JENTADUETO XR	LINAGLIPTIN-METFORMIN HCL TAB ER 24HR 2.5-1000 MG	27992502407520	Brand
JENTADUETO XR	LINAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-1000 MG	27992502407530	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 30 day supply, intolerance, or contraindication to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

Product Name:Kazano, Brand Alogliptin/Metformin, Brand Kombiglyze XR , Generic saxagliptin/metformin ER, Nesina, Alogliptin, Brand Onglyza, Generic saxagliptin, Oseni, Alogliptin/Pioglitazone, Zituvio, Brand Sitagliptin, Brand Sitagliptin/Metformin, Zituvimet, Zituvimet XR

Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
KAZANO	ALOGLIPTIN-METFORMIN HCL TAB 12.5-500 MG	27992502100320	Generic
ALOGLIPTIN/METFORMIN HCL	ALOGLIPTIN-METFORMIN HCL TAB 12.5-500 MG	27992502100320	Generic
KAZANO	ALOGLIPTIN-METFORMIN HCL TAB 12.5-1000 MG	27992502100330	Generic
ALOGLIPTIN/METFORMIN HCL	ALOGLIPTIN-METFORMIN HCL TAB 12.5-1000 MG	27992502100330	Generic
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 2.5-1000 MG	27992502607520	Brand

KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-500 MG	27992502607530	Brand
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-1000 MG	27992502607540	Brand
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 6.25 MG (BASE EQUIV)	27550010100310	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 6.25 MG (BASE EQUIV)	27550010100310	Generic
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 12.5 MG (BASE EQUIV)	27550010100320	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 12.5 MG (BASE EQUIV)	27550010100320	Generic
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 25 MG (BASE EQUIV)	27550010100330	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 25 MG (BASE EQUIV)	27550010100330	Generic
ONGLYZA	SAXAGLIPTIN HCL TAB 2.5 MG (BASE EQUIV)	27550065100320	Brand
ONGLYZA	SAXAGLIPTIN HCL TAB 5 MG (BASE EQUIV)	27550065100330	Brand
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-15 MG	27994002100320	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-15 MG	27994002100320	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-30 MG	27994002100325	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-30 MG	27994002100325	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-45 MG	27994002100330	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-45 MG	27994002100330	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-15 MG	27994002100340	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-15 MG	27994002100340	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-30 MG	27994002100345	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-30 MG	27994002100345	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-45 MG	27994002100350	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-45 MG	27994002100350	Generic
SAXAGLIPTIN HYDROCHLORIDE	SAXAGLIPTIN HCL TAB 2.5 MG (BASE EQUIV)	27550065100320	Generic

SAXAGLIPTIN HYDROCHLORIDE	SAXAGLIPTIN HCL TAB 5 MG (BASE EQUIV)	27550065100330	Generic
SAXAGLIPTIN HYDROCHLORIDE/METFORMIN HYDROCHLORIDE ER	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 2.5-1000 MG	27992502607520	Generic
SAXAGLIPTIN HYDROCHLORIDE/METFORMIN HYDROCHLORIDE ER	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-1000 MG	27992502607540	Generic
SAXAGLIPTIN HYDROCHLORIDE/METFORMIN HYDROCHLORIDE ER	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-500 MG	27992502607530	Generic
ZITUVIO	SITAGLIPTIN TAB 25 MG	27550070000320	Brand
ZITUVIO	SITAGLIPTIN TAB 50 MG	27550070000330	Brand
ZITUVIO	SITAGLIPTIN TAB 100 MG	27550070000340	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 25 MG	27550070000320	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 50 MG	27550070000330	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 100 MG	27550070000340	Brand
SITAGLIPTIN/METFORMIN HYDROCHLORIDE	SITAGLIPTIN FREE BASE-METFORMIN HCL TAB 50-500 MG	27992502690320	Brand
SITAGLIPTIN/METFORMIN HYDROCHLORIDE	SITAGLIPTIN FREE BASE-METFORMIN HCL TAB 50-1000 MG	27992502690330	Brand
ZITUVIMET	SITAGLIPTIN FREE BASE-METFORMIN HCL TAB 50-500 MG	27992502690320	Brand
ZITUVIMET	SITAGLIPTIN FREE BASE-METFORMIN HCL TAB 50-1000 MG	27992502690330	Brand
ZITUVIMET XR	SITAGLIPTIN FREE BASE-METFORMIN HCL TAB ER 24HR 50-500 MG	27992502697520	Brand
ZITUVIMET XR	SITAGLIPTIN FREE BASE-METFORMIN HCL TAB ER 24HR 50-1000 MG	27992502697530	Brand
ZITUVIMET XR	SITAGLIPTIN FREE BASE-METFORMIN HCL TAB ER 24HR 100-1000 MG	27992502697540	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 30 day supply, intolerance, or contraindication to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

AND

3 - Trial and failure of a minimum 90 day supply, intolerance, or contraindication to any one of the following preferred brands:

- Januvia
- Janumet
- Janumet XR

AND

4 - Trial and failure of a minimum 90 day supply, intolerance, or contraindication to any one of the following preferred brands:

- Jentadueto
- Jentadueto XR
- Tradjenta

Product Name:Kazano, Brand Alogliptin/Metformin, Brand Kombiglyze XR, Nesina, Alogliptin, Brand Onglyza, Oseni, Alogliptin/Pioglitazone, Zituvio, Brand Sitagliptin	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
KAZANO	ALOGLIPTIN-METFORMIN HCL TAB 12.5-500 MG	27992502100320	Generic

ALOGLIPTIN/METFORMIN HCL	ALOGLIPTIN-METFORMIN HCL TAB 12.5-500 MG	27992502100320	Generic
KAZANO	ALOGLIPTIN-METFORMIN HCL TAB 12.5-1000 MG	27992502100330	Generic
ALOGLIPTIN/METFORMIN HCL	ALOGLIPTIN-METFORMIN HCL TAB 12.5-1000 MG	27992502100330	Generic
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 2.5-1000 MG	27992502607520	Brand
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-500 MG	27992502607530	Brand
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-1000 MG	27992502607540	Brand
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 6.25 MG (BASE EQUIV)	27550010100310	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 6.25 MG (BASE EQUIV)	27550010100310	Generic
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 12.5 MG (BASE EQUIV)	27550010100320	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 12.5 MG (BASE EQUIV)	27550010100320	Generic
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 25 MG (BASE EQUIV)	27550010100330	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 25 MG (BASE EQUIV)	27550010100330	Generic
ONGLYZA	SAXAGLIPTIN HCL TAB 2.5 MG (BASE EQUIV)	27550065100320	Brand
ONGLYZA	SAXAGLIPTIN HCL TAB 5 MG (BASE EQUIV)	27550065100330	Brand
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-15 MG	27994002100320	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-15 MG	27994002100320	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-30 MG	27994002100325	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-30 MG	27994002100325	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-45 MG	27994002100330	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-45 MG	27994002100330	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-15 MG	27994002100340	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-15 MG	27994002100340	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-30 MG	27994002100345	Generic

OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-30 MG	27994002100345	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-45 MG	27994002100350	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-45 MG	27994002100350	Generic
ZITUVIO	SITAGLIPTIN TAB 25 MG	27550070000320	Brand
ZITUVIO	SITAGLIPTIN TAB 50 MG	27550070000330	Brand
ZITUVIO	SITAGLIPTIN TAB 100 MG	27550070000340	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 25 MG	27550070000320	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 50 MG	27550070000330	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 100 MG	27550070000340	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure of a minimum 30 day supply, intolerance, or contraindication to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

AND

3 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure of a minimum 90 day supply, intolerance, or contraindication to any one of the following preferred brands:

- Januvia
- Janumet
- Janumet XR

AND

4 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure of a minimum 90 day supply, intolerance, or contraindication to any one of the following preferred brands:

- Jentadueto
- Jentadueto XR
- Tradjenta

3 . References

1. Januvia Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2023.
2. Janumet Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2022.
3. Onglyza Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. October 2019.
4. Tradjenta Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.
5. Janumet XR Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2022.
6. Jentadueto Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.
7. Jentadueto XR Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.
8. Oseni Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. December 2023.
9. Kazano Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. July 2023.
10. Nesina Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. July 2023.
11. Kombiglyze XR Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. October 2019.
12. Saxaglipitin hydrochloride/metformin hydrochloride ER Prescribing Information . Dr. Reddys Laboratories Princeton, NJ. January 2023
13. Saxaglipitin hydrochloride/metformin hydrochloride ER Prescribing Information . Aurobindo Pharma USA, Inc. East Windsor, NJ. April 2023
14. Zituvio Prescribing Information. Zydus Lifesciences Limited, Pharmez, Matoda, Amedabad, India. November 2023.
15. Zituvimet Prescribing Information. Zydus Lifesciences Limited, Pharmez, Matoda, Amedabad, India. July 2024.
16. Zituvimet XR Prescribing Information. Zydus Lifesciences Limited, Pharmez, Matoda, Amedabad, India. July 2024.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228843
Guideline Name	Duexis (ibuprofen and famotidine) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Duexis (ibuprofen/famotidine)
Osteoarthritis, rheumatoid arthritis, and gastrointestinal ulcers Indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and /or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. Controlled trials do not extend beyond 6 months.

2 . Criteria

Product Name:Brand Duexis, generic ibuprofen-famotidine F	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUEXIS	IBUPROFEN-FAMOTIDINE TAB 800-26.6 MG	66109902320340	Brand
IBUPROFEN/FAMOTIDINE	IBUPROFEN-FAMOTIDINE TAB 800-26.6 MG	66109902320340	Generic

Approval Criteria

1 - One of the following diagnoses:

- Osteoarthritis
- Rheumatoid Arthritis

AND

2 - One of the following [2]:

- History of peptic ulcer disease
- History of gastrointestinal (GI) bleeding, obstruction, or perforation
- Erosive esophagitis
- Used in combination with aspirin

AND

3 - History of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generics:

- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam
- sulindac
- tolmetin

- diclofenac

AND

4 - History of a minimum 30 day trial and failure, or intolerance to two of the following generic H2-receptor antagonists:

- cimetidine
- famotidine
- nizatidine
- ranitidine

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with brand Duexis or generic ibuprofen-famotidine instead of taking individual products in combination

Product Name:Brand Duexis, generic ibuprofen-famotidine NF	
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DUEXIS	IBUPROFEN-FAMOTIDINE TAB 800-26.6 MG	66109902320340	Brand
IBUPROFEN/FAMOTIDINE	IBUPROFEN-FAMOTIDINE TAB 800-26.6 MG	66109902320340	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following diagnoses:

- Osteoarthritis
- Rheumatoid Arthritis

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following [2]:

- History of peptic ulcer disease
- History of gastrointestinal (GI) bleeding, obstruction, or perforation
- Erosive esophagitis
- Used in combination with aspirin

AND

3 - Paid claims or submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generics:

- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam
- sulindac
- tolmetin
- diclofenac

AND

4 - Paid claims or submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generic H2-receptor antagonists:

- cimetidine
- famotidine
- nizatidine
- ranitidine

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with brand Duexis or generic ibuprofen-famotidine instead of taking individual products in combination

3 . References

1. Duexis [prescribing information]. Deerfield, IL: Horizon Medicines, LLC; April 2021.
2. Solomon C. Upper Gastrointestinal Bleeding Due to a Peptic Ulcer. N Engl J Med. 2016;374:2367-2376.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228400
Guideline Name	Duobrii (halobetasol propionate and tazarotene) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Duobrii (halobetasol propionate and tazarotene)
Plaque Psoriasis Indicated for the topical treatment of plaque psoriasis in adults.

2 . Criteria

Product Name:Duobrii			
Approval Length	12 month(s)		
Guideline Type	Prior Authorization		
Product Name	Generic Name	GPI	Brand/Generic

DUOBRII	HALOBETASOL PROPIONATE-TAZAROTENE LOTION 0.01-0.045%	90559902484120	Brand

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Prescribed by or in consultation with a dermatologist

AND

3 - Trial and failure, intolerance, or contraindication to ALL of the following:

- One high potency corticosteroid topical treatment (e.g., halobetasol propionate, clobetasol propionate, fluocinonide)
- Tazarotene
- Enstilar foam, Wynzora, Taclonex suspension/ointment, or generic Taclonex

Product Name:Duobrii	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DUOBRII	HALOBETASOL PROPIONATE-TAZAROTENE LOTION 0.01-0.045%	90559902484120	Brand

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Prescribed by or in consultation with a dermatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, intolerance or contraindication to ALL of the following:

- One high potency corticosteroid topical treatment (e.g., halobetasol propionate, clobetasol propionate, fluocinonide)
- Tazarotene
- Enstilar foam, Wynzora, Taclonex suspension/ointment, or generic Taclonex

3 . Background

Clinical Practice Guidelines

Table 1. Relative Potency of Selected Topical Corticosteroid Products [3]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25

	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . References

1. Duobrii Prescribing Information. Bausch Health Americas, Inc. Bridgewater, NJ. January 2020.
2. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
3. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023; Epub ahead of print.

Prior Authorization Guideline

Guideline ID	GL-233233
Guideline Name	Dupixent (dupilumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Dupixent (dupilumab)
Atopic Dermatitis (AD) Indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids. **Asthma** Indicated as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitations of use: Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus. **Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)** Indicated as an add-on maintenance treatment in patients 12 years of age and older with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP). **Eosinophilic Esophagitis (EoE)** Indicated for the treatment of adult and pediatric patients

aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).

Prurigo Nodularis (PN) Indicated for the treatment of adult patients with prurigo nodularis (PN).

Chronic Obstructive Pulmonary Disease (COPD) Indicated in COPD with evidence of type 2 inflammation.

2 . Criteria

Product Name:Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)

- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

3 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to at least ONE of the following [2]:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

4 - Patient is 6 months of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

Notes	*Product may require step therapy

Product Name:Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand

DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in BSA involvement from baseline
- Reduction in SCORAD index value from baseline [A]

Product Name:Dupixent	
Diagnosis	Eosinophilic Asthma
Approval Length	6 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of moderate to severe asthma

AND

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [C, D]

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [4, 5, 7]

OR

3.2 Prior asthma-related hospitalization within the past 12 months [4, 5, E]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Patient is 6 years of age or older but less than 12 years of age

AND

4.1.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1.2.1 Both of the following:

- Medium-dose inhaled corticosteroid (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.1.2.2 One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone

propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg])

OR

4.2 Both of the following:

4.2.1 Patient is 12 years of age or older

AND

4.2.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.2.2.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.2.2.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg])

AND

5 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name:Dupixent	
Diagnosis	Eosinophilic Asthma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name:Dupixent	
Diagnosis	Oral Corticosteroid Dependent Asthma
Approval Length	6 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of moderate to severe asthma

AND

2 - Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 6 years of age or older but less than 12 years of age

AND

3.1.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

3.1.2.1 Both of the following:

- Medium-dose inhaled corticosteroid (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

3.1.2.2 One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg])

OR

3.2 Both of the following:

3.2.1 Patient is 12 years of age or older

AND

3.2.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

3.2.2.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

3.2.2.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone

propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg])

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name:Dupixent	
Diagnosis	Oral Corticosteroid Dependent Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], reduction in oral corticosteroid dose)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name:Dupixent	
Diagnosis	Chronic rhinosinusitis with nasal polyposis (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

AND

2 - Patient is 12 years of age or older

AND

2 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [8, 9]

AND

3 - Used in combination with another agent for CRSwNP [F]

AND

5 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name:Dupixent	
Diagnosis	Chronic rhinosinusitis with nasal polyposis (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NC; 0-3 scale])

AND

2 - Used in combination with another agent for CRSwNP [F]

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name:Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand

Approval Criteria

1 - Diagnosis of eosinophilic esophagitis (EoE)

AND

2 - Patient has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, heartburn, abdominal pain) [13-15]

AND

3 - Patient has at least 15 intraepithelial eosinophils per high power field (HPF) [1, 13-15]

AND

4 - Other causes of esophageal eosinophilia have been excluded [13-15]

AND

5 - Both of the following:

- Patient is at least 1 year of age
- Patient weighs at least 15 kg

AND

6 - Trial and failure (of a minimum 8-week duration), contraindication, or intolerance to one of the following:

- Proton pump inhibitors (e.g., pantoprazole, omeprazole)
- Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone)

AND

7 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Allergist/Immunologist

Product Name:Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline [1, 13-15]:

- Symptoms (e.g., dysphagia, food impaction, heartburn, chest pain)
- Histologic measures (e.g., esophageal intraepithelial eosinophil count)
- Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures)

Product Name:Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of prurigo nodularis (PN)

AND

2 - Patient has at least 20 nodular lesions

AND

3 - Trial and failure, contraindication, or intolerance to one medium or higher potency topical corticosteroid [16, 17]

AND

4 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Dermatologist

Product Name:Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in the number of nodular lesions from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Dupixent	
Diagnosis	Chronic obstructive pulmonary disease (COPD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2 - Presence of Type 2 inflammation evidenced by blood eosinophils greater than or equal to 300 cells per microliter at baseline

AND

3 - Patient is receiving one of the following therapies at maximally tolerated doses

- Triple therapy (i.e., an inhaled corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA) and a long-acting beta agonist (LABA)
- If ICS are contraindicated, a LAMA and a LABA

AND

4 - Patient must have post-bronchodilator forced expiratory volume [FEV1] / forced vital capacity [FVC] ratio less than 0.70

AND

5 - Patient has had one of the following within the past 12 months:

5.1 At least two exacerbations where systemic corticosteroids [intramuscular, intravenous, or oral (e.g., prednisone)] were required at least once

OR

5.2 COPD-related hospitalization

AND

6 - Patient experiences dyspnea during everyday activities (e.g., needs to stop for breath when walking on level ground) [G]

Product Name:Dupixent	
Diagnosis	Chronic obstructive pulmonary disease (COPD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand

DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., improved lung function, a reduction in COPD exacerbations)

AND

2 - Patient continues to receive one of the following therapies:

- Triple therapy (i.e., an inhaled corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA) and a long-acting beta agonist (LABA)
- If ICS are contraindicated, a LAMA and a LABA

3 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
	Amcinonide	Cream, lotion, ointment	0.1

High Potency	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [7]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High

Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country - specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [5] The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [5]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
-	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Beclometasone dipropionate (pMDI, extrafine particle, HFA)	50-100	> 100-200	> 200
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Budesonide (nebules)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle*, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50		n.a.
Fluticasone propionate (DPI)	50-100	> 100-200	> 200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	> 100-200	> 200
Mometasone furoate (pMDI, standard particle, HFA)	100		200

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply

potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [10, 11] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [12]
B. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy.
C. In AS Trial 2, reductions in exacerbations were significant in the subgroup of subjects with baseline blood eosinophils greater than or equal to 150 cells/mcL. In subjects with baseline blood eosinophil count less than 150 cells/mcL, similar severe exacerbation rates were observed between Dupixent and placebo. [1]
D. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [3]
E. Recommendation inferred from the national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.
F. Other agents used for CRSwNP include intranasal corticosteroids and nasal saline.
G. In the BOREAS trial, the inclusion criteria included a grade of greater than or equal to 2 on the Medical Research Council (MRC) Dyspnea Scale. [18,19]

5 . References

1. Dupixent Prescribing Information. Sanofi-aventis U.S. LLC. Bridgewater, NJ. January 2024.
2. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
3. Institute for Clinical and Economic Review (ICER). Biologic therapies for treatment of asthma associated with type 2 inflammation: effectiveness, value, and value-based price benchmarks. https://icer.org/wp-content/uploads/2020/10/ICER_Asthma-Final-Report_Unredacted_08122020.pdf. Published December 20, 2018. Accessed March 2, 2021.
4. Wenzel S, Castro M, Corren J, et al. Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium-to-high dose inhaled corticosteroids plus a long-acting B2 agonist: a randomized double-blind placebo-controlled pivotal phase 2b dose-ranging trial. Lancet. 2016;388:31-44.
5. Castro M, Corren J, Pavord ID, et al. Dupilumab efficacy and safety in moderate-to-severe uncontrolled asthma. N Engl J Med. 2018; 378(26):2486-96.
6. Rabe KF, Nair P, Brusselle G, et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. N Engl J Med. 2018; 378(26):2475-85.
7. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2023 update). 2023 www.ginasthma.org. Accessed April 2024.
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9. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. Int Forum Allergy Rhinol. 2016 Feb; Suppl 1:S22-209.
10. European Task Force on Atopic Dermatitis. Severity scoring of atopic dermatitis: the SCORAD index. Consensus report of the European Task Force on atopic dermatitis. Dermatology. 1993; 186:23-31.
11. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. Lancet 2017; 389(10086)(suppl):2287-2303.
12. Oranje AP. Practical issues on interpretation of scoring atopic dermatitis: SCORAD index, objective SCORAD, patient-oriented SCORAD and three-item severity score. Curr Probl Dermatol. 2011; 41:149-55.
13. Gonsalves NP, Aceves SS. Diagnosis and treatment of eosinophilic esophagitis. J Allergy Clin Immunol. 2020;145(1):1-7.
14. Hirano I, Chan ES, Rank MA, et al. AGA Institute and the Joint Task Force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis. Gastroenterology. 2020;158:1776-86.
15. Dellon ES, Khoury P, Muir AB, et al. A clinical severity index for eosinophilic esophagitis: development, consensus, and future directions. Gastroenterology. 2022;1-18 [Epub ahead of print].
16. Williams KA, Huang AH, Belzberg M, et al. Prurigo nodularis: pathogenesis and management. J Am Acad Dermatol. 2020;83(6):1567-75.
17. Leis M, Fleming P, Lynde CW. Prurigo nodularis: review and emerging treatments. Skin Therapy Lett. 2021;26(3):5-8.
18. BOREAS trial | Pivotal Study to Assess the Efficacy, Safety and Tolerability of Dupilumab in Patients With Moderate-to-severe COPD With Type 2 Inflammation | https://clinicaltrials.gov/study/NCT03930732
19. Modified Medical Research Council (mMRC) dyspnea scale | https://www.uptodate.com/contents/image?imageKey=PULM/86426

20. NOTUS trial | Pivotal Study to Assess the Efficacy, Safety and Tolerability of Dupilumab in Patients With Moderate to Severe COPD With Type 2 Inflammation | https://clinicaltrials.gov/study/NCT04456673?term=notus&rank=1

6 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228637
Guideline Name	Duvyzat (givinostat)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Duvyzat (givinostat)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

2 . Criteria

Product Name:Duvyzat	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUVYZAT	GIVINOSTAT HCL ORAL SUSP 8.86 MG/ML	74603025201820	Brand

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - One of the following:

2.1 Patient has a confirmed mutation of the dystrophin gene

OR

2.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

3 - Patient is 6 years of age or older

AND

4 - Patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to initiating Duvyzat

AND

5 - Requested drug will be used concomitantly with a corticosteroid regimen (e.g., prednisone/prednisolone, Emflaza [deflazacort], Agamree)

AND

6 - Prescribed by or in consultation with a pediatric neurologist with expertise in treating DMD

Product Name:Duvyzat	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUVYZAT	GIVINOSTAT HCL ORAL SUSP 8.86 MG/ML	74603025201820	Brand

Approval Criteria

1 - Patient has experienced a benefit from therapy (e.g., improvement in preservation of muscle strength)

AND

2 - Patient is maintaining ambulatory status without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

3 - Patient continues to receive concomitant corticosteroid regimen (e.g., prednisone/prednisolone, Emflaza [deflazacort], Agamree)

3 . Endnotes

A. Approximately 70% of individuals with DMD have a single-exon or multi-exon deletion or duplication in the dystrophin gene, dystrophin gene deletion, and duplication testing is usually the first confirmatory test. If genetic testing does not confirm a clinical diagnosis of DMD, then a muscle biopsy sample should be tested for the presence of dystrophin protein by immunohistochemistry of tissue cryosections or by western blot of a muscle protein extract. [2]

B. Prednisone 0.75 mg/kg/d should be considered the optimal prednisone dose in DMD. Over 12 months, prednisone 10 mg/kg/weekend is equally effective, although long term outcomes of this alternative regimens are unknown. [3]

4 . References

1. Duvyzat Prescribing Information. ITF Therapeutics, LLC. Concord, MA. March 2024.
2. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. The Lancet Neurology. 2018;17(3):251-267.
3. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(5):465-72.

Prior Authorization Guideline

Guideline ID	GL-228639
Guideline Name	Dysport (abobotulinumtoxinA)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Dysport (abobotulinumtoxinA)
Cervical Dystonia Indicated for the treatment of cervical dystonia in adults. **Spasticity** Indicated for the treatment of spasticity in patients 2 years of age and older. **Cosmetic Uses [Non-approvable Use]** Indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients less than 65 years of age. Note: This indication is generally a plan exclusion. Drugs prescribed to primarily improve or otherwise modify the member's external appearance are excluded from coverage, as this is considered a cosmetic use.

2 . Criteria

Product Name:Dysport

Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DYSPORT	ABOBOTULINUMTOXINA FOR INJ 300 UNIT	74400020032115	Brand
DYSPORT	ABOBOTULINUMTOXINA FOR INJ 500 UNIT	74400020032120	Brand

Approval Criteria

1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis) [2, 3]

Product Name:Dysport	
Diagnosis	Spasticity
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DYSPORT	ABOBOTULINUMTOXINA FOR INJ 300 UNIT	74400020032115	Brand
DYSPORT	ABOBOTULINUMTOXINA FOR INJ 500 UNIT	74400020032120	Brand

Approval Criteria

1 - Diagnosis of spasticity [3]

AND

2 - Patient is 2 years of age or older

Product Name:Dysport

Diagnosis	All indications listed above
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DYSPORT	ABOBOTULINUMTOXINA FOR INJ 300 UNIT	74400020032115	Brand
DYSPORT	ABOBOTULINUMTOXINA FOR INJ 500 UNIT	74400020032120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have elapsed since the last treatment [A]

Product Name:Dysport	
Diagnosis	Cosmetic Uses
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DYSPORT	ABOBOTULINUMTOXINA FOR INJ 300 UNIT	74400020032115	Brand
DYSPORT	ABOBOTULINUMTOXINA FOR INJ 500 UNIT	74400020032120	Brand

Approval Criteria

1 - Requests for coverage of any Dysport product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only.

3 . Endnotes

A. In the pivotal clinical trial, doses of 500 Units and 1000 Units were divided among selected muscles. Repeat treatment should be administered when the effect of a previous injection has diminished, but no sooner than 12 weeks after the previous injection. A majority of patients in clinical studies were retreated between 12-16 weeks; however some patients had a longer duration of response, i.e., 20 weeks. [1]

4 . References

1. Dysport Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. January 2023.
2. Truong D, Duane DD, Jankovic J, et al. Efficacy and safety of botulinum type A toxin (Dysport) in cervical dystonia: results of the first US randomized, double-blind, placebo-controlled study. Mov Disord. 2005;20(7):783-791.
3. Simpson D, Hallett M, Ashman E et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology. 2016;86(19):1818-1826.

Prior Authorization Guideline

Guideline ID	GL-233261
Guideline Name	Ebglyss (lebrikizumab-lbkz)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/21/2024
P&T Revision Date:	12/18/2024

1 . Indications

Drug Name: Ebglyss (lebrikizumab-lbkz)
Atopic Dermatitis (AD) Indicated for the treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Ebglyss can be used with or without topical corticosteroids.

2 . Criteria

Product Name:Ebglyss	
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EBGLYSS	LEBRIKIZUMAB-LBKZ SUBCUTANEOUS SOLN AUTO-INJECT 250 MG/2ML	9027304010D520	Brand
EBGLYSS	LEBRIKIZUMAB-LBKZ SOLUTION PREFILLED SYRINGE 250 MG/2ML	9027304010E520	Brand

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

3 - Both of the following:

- Patient is 12 years of age or older
- Patient weighs at least 40 kg

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to TWO of the following [2]:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

6 - Trial and failure, contraindication, or intolerance to TWO of the following:

- Adbry (tralokizumab-ldrm)
- Dupixent (dupilumab)
- Cibinqo (abrocitinib)
- Rinvoq (upadacitinib)

Product Name:Ebglyss	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EBGLYSS	LEBRIKIZUMAB-LBKZ SUBCUTANEOUS SOLN AUTO-INJECT 250 MG/2ML	9027304010D520	Brand
EBGLYSS	LEBRIKIZUMAB-LBKZ SOLUTION PREFILLED SYRINGE 250 MG/2ML	9027304010E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least ONE of the following [1-2]:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

3 . Background

Benefit/Coverage/Program Information

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025

	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [3, 4] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [5]

5 . References

1. Ebglyss Prescribing Information. Eli Lilly and Co. Indianapolis, IN. September, 2024.
2. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
3. European Task Force on Atopic Dermatitis. Severity scoring of atopic dermatitis: the SCORAD index. Consensus report of the European Task Force on atopic dermatitis. Dermatology. 1993; 186:23-31.
4. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. Lancet 2017; 389(10086)(suppl):2287-2303.
5. Oranje AP. Practical issues on interpretation of scoring atopic dermatitis: SCORAD index, objective SCORAD, patient-oriented SCORAD and three-item severity score. Curr Probl Dermatol. 2011; 41:149-55.

6 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228401
Guideline Name	Egrifta (tesamorelin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Egrifta SV (tesamorelin)
Excess Abdominal Fat Reduction in HIV-associated Lipodystrophy Indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. Limitations of use: 1) Long-term cardiovascular safety of EGRIFTA SV has not been established. Consider risk/benefit of continuation of treatment in patients who have not had a reduction in visceral adipose tissue. 2) Not indicated for weight loss management as it has a weight neutral effect. 3) There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking EGRIFTA SV.

2 . Criteria

Product Name:Egrifta SV	
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EGRIFTA SV	TESAMORELIN ACETATE FOR INJ 2 MG (BASE EQUIV)	30150085102130	Brand

Approval Criteria

1 - Diagnosis of HIV-associated lipodystrophy

AND

2 - Patient is 18 years of age or older [A]

AND

3 - One of the following: [B]

- Waist-circumference of greater than or equal to 95 cm (37.4 inches) in men
- Waist-circumference of greater than or equal to 94 cm (37 inches) for women

AND

4 - One of the following: [B]

- Waist-to-hip ratio of greater than or equal to 0.94 for men
- Waist-to-hip ratio of greater than or equal to 0.88 for women

AND

5 - Body mass index (BMI) of greater than 20 kg/m^2 [B]

AND

6 - Fasting blood glucose (FBG) levels less than or equal to 150 mg/dL (8.33 mmol/L) [B]

AND

7 - Patient has been on a stable regimen of antiretrovirals (e.g., nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, Protease Inhibitors, Integrase Inhibitors) for at least 8 weeks [C]

Product Name:Egrifta SV	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EGRIFTA SV	TESAMORELIN ACETATE FOR INJ 2 MG (BASE EQUIV)	30150085102130	Brand

Approval Criteria

1 - Patient demonstrates clinical improvement (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance, etc.) while on therapy

3 . Endnotes

A. Study sponsors requested a waiver for pediatric studies in children less than 18 years of age, and this waiver was granted by the FDA due to concerns that among patients with open epiphyses, excess growth hormone and IGF-1 may result in linear growth acceleration and excessive growth. [2]
B. Both pivotal studies included patients 18 to 65 years of age (mean age, 48 years) who met the waist circumference criteria [95 cm (37.4 inches) or greater for men; 94 cm (37 inches) or greater for women], who met the waist-to-hip ratio criteria (0.94 or greater for men; 0.88 or greater for women), who had a fasting blood glucose of less than 150 mg/dL (8.33 mmol/L) criteria, and who had been on a stable antiretroviral regimen for at least 8 weeks. Patients with a BMI (body mass index) of 20 kg/m^2 or less and patients with diabetes [fasting blood glucose (FBG) levels > 150 mg/dL] were among those excluded. [2-6]

C. The 8 weeks of antiretroviral regimen listed in the criteria is based on the inclusion criteria in the pivotal study. [2-6]

4 . References

1. Egrifta SV Prescribing Information. Theratechnologies, Inc. Montreal, Canada. February 2024.
2. Egrifta FDA Medical Review. September 15, 2010. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022505Orig1s000TOC.cfm. Accessed May 20, 2021.
3. Falutz J, Allas S, Blot K, et al. Metabolic effects of a growth hormone-releasing factor in patients with HIV. N Engl J Med. 2007;357:2359-2370.
4. Falutz J, Allas S, Mamputu JC, et al. Long-term safety and effects of tesamorelin, a growth hormone-releasing factor analogue, in HIV patients with abdominal fat accumulation. AIDS. 2008;22:1719-1728.
5. Falutz J, Mamputu JC, Potvin D, et al. Effects of tesamorelin (TH9507), a growth hormone-releasing factor analog, in HIV-infected patients with excess abdominal fat: a pooled analysis of two multicenter, double-blind placebo-controlled phase 3 trials with safety extension data. J Clin Endocrinol Metab. 2010;95:4291-4304.
6. Falutz J, Potvin D, Mamputu JC, et al. Effects of tesamorelin, a growth hormone-releasing factor, in HIV-infected patients with abdominal fat accumulation: a randomized placebo-controlled trial with a safety extension. J Acquir Immune Defic Syndr. 2010; 53(3):311-22.

Prior Authorization Guideline

Guideline ID	GL-228642
Guideline Name	Elaprase (idursulfase)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Elaprase (idursulfase) [1]
Hunter Syndrome Is indicated for patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). Elaprase has been shown to improve walking capacity in patients 5 years and older. In patients 16 months to 5 years of age, no data are available to demonstrate improvement in disease-related symptoms or long term clinical outcome; however, treatment with Elaprase has reduced spleen volume similarly to that of adults and children 5 years of age and older. The safety and efficacy of Elaprase have not been established in pediatric patients less than 16 months of age.

2 . Criteria

Product Name:Elaprase (idursulfase)	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ELAPRASE	IDURSULFASE SOLN FOR IV INFUSION 6 MG/3ML (2 MG/ML)	30906850002020	Brand

Approval Criteria

1 - Diagnosis of Hunter syndrome (Mucopolysaccharidosis II, MPS II)

Product Name:Elaprase (idursulfase)	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ELAPRASE	IDURSULFASE SOLN FOR IV INFUSION 6 MG/3ML (2 MG/ML)	30906850002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Elaprase Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA. October 2021.

Prior Authorization Guideline

Guideline ID	GL-228404
Guideline Name	Elyxyb (celecoxib) Oral Solution - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Elyxyb (celecoxib) Oral Solution
Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of use: ELYXYB is not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name:Elyxyb			
Approval Length	12 month(s)		
Guideline Type	Prior Authorization		
Product Name	Generic Name	GPI	Brand/Generic

ELYXYB	CELECOXIB ORAL SOLN 120 MG/4.8ML (25 MG/ML)	67604030002020	Brand

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Trial and failure, contraindication or intolerance to two of the following generics:

- Almotriptan tablet
- Eletriptan tablet
- Frovatriptan tablet
- Naratriptan tablet
- Rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)
- Sumatriptan tablet/nasal spray
- Zolmitriptan tablet/zolmitriptan ODT

Product Name:Elyxyb	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ELYXYB	CELECOXIB ORAL SOLN 120 MG/4.8ML (25 MG/ML)	67604030002020	Brand

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to two of the following generics:

- Almotriptan tablet

- Eletriptan tablet
- Frovatriptan tablet
- Naratriptan tablet
- Rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)
- Sumatriptan tablet/nasal spray
- Zolmitriptan tablet/zolmitriptan ODT

3 . References

1. Elyxyb Prescribing Information. Dr. Reddy's Laboratories Limited. Telangana, India. October 2021.

Prior Authorization Guideline

Guideline ID	GL-228406
Guideline Name	Emergency Agents for the Treatment of Severe Hypoglycemia - ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Glucagen
Severe Hypoglycemia Indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes. **Diagnostic Aid** GlucaGen is indicated as a diagnostic aid for use during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in adult patients.
Drug Name: Glucagon
Severe Hypoglycemia Indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes mellitus. **Diagnostic Aid** Indicated as a diagnostic aid for use during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in adult patients.
Drug Name: Gvoke

Severe Hypoglycemia Indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above.

2 . Criteria

Product Name:Glucagen, Glucagon (manufactured by Lilly), Gvoke	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
GLUCAGEN HYPOKIT	GLUCAGON HCL (RDNA) FOR INJ 1 MG (BASE EQUIV)	27300010152110	Brand
GLUCAGEN DIAGNOSTIC	GLUCAGON HCL (RDNA) DIAGNOSTIC FOR INJ 1 MG (BASE EQUIV)	94200041152110	Brand
GVOKE HYPOPEN 1-PACK	GLUCAGON SUBCUTANEOUS SOLUTION AUTO-INJECTOR 0.5 MG/0.1ML	2730001000D520	Brand
GVOKE HYPOPEN 2-PACK	GLUCAGON SUBCUTANEOUS SOLUTION AUTO-INJECTOR 0.5 MG/0.1ML	2730001000D520	Brand
GVOKE HYPOPEN 1-PACK	GLUCAGON SUBCUTANEOUS SOLUTION AUTO-INJECTOR 1 MG/0.2ML	2730001000D530	Brand
GVOKE HYPOPEN 2-PACK	GLUCAGON SUBCUTANEOUS SOLUTION AUTO-INJECTOR 1 MG/0.2ML	2730001000D530	Brand
GVOKE PFS	GLUCAGON SUBCUTANEOUS SOLN PREF SYRINGE 0.5 MG/0.1ML	2730001000E520	Brand
GVOKE PFS	GLUCAGON SUBCUTANEOUS SOLN PREF SYRINGE 1 MG/0.2ML	2730001000E530	Brand
GVOKE KIT	GLUCAGON SUBCUTANEOUS SOLN 1 MG/0.2ML	27300010002020	Brand
GLUCAGON EMERGENCY KIT	GLUCAGON (RDNA) FOR INJ KIT 1 MG	27300010106410	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure within the past 180 days, or intolerance to one of the following preferred drugs:

- Baqsimi
- Glucagon (manufactured by Fresenius)
- Zegalogue
- generic glucagon kit

Product Name:Glucagen, Glucagon (manufactured by Lilly), Gvoke	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLUCAGEN HYPOKIT	GLUCAGON HCL (RDNA) FOR INJ 1 MG (BASE EQUIV)	27300010152110	Brand
GLUCAGEN DIAGNOSTIC	GLUCAGON HCL (RDNA) DIAGNOSTIC FOR INJ 1 MG (BASE EQUIV)	94200041152110	Brand
GVOKE HYPOPEN 1-PACK	GLUCAGON SUBCUTANEOUS SOLUTION AUTO-INJECTOR 0.5 MG/0.1ML	2730001000D520	Brand
GVOKE HYPOPEN 2-PACK	GLUCAGON SUBCUTANEOUS SOLUTION AUTO-INJECTOR 0.5 MG/0.1ML	2730001000D520	Brand
GVOKE HYPOPEN 1-PACK	GLUCAGON SUBCUTANEOUS SOLUTION AUTO-INJECTOR 1 MG/0.2ML	2730001000D530	Brand
GVOKE HYPOPEN 2-PACK	GLUCAGON SUBCUTANEOUS SOLUTION AUTO-INJECTOR 1 MG/0.2ML	2730001000D530	Brand
GVOKE PFS	GLUCAGON SUBCUTANEOUS SOLN PREF SYRINGE 0.5 MG/0.1ML	2730001000E520	Brand
GVOKE PFS	GLUCAGON SUBCUTANEOUS SOLN PREF SYRINGE 1 MG/0.2ML	2730001000E530	Brand
GVOKE KIT	GLUCAGON SUBCUTANEOUS SOLN 1 MG/0.2ML	27300010002020	Brand
GLUCAGON EMERGENCY KIT	GLUCAGON (RDNA) FOR INJ KIT 1 MG	27300010106410	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure within the past 180 days, or intolerance to one of the following preferred drugs:

- Baqsimi
- Glucagon (manufactured by Fresenius)
- Zegalogue
- generic glucagon kit

3 . References

1. GlucaGen Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. March 2021.
2. Glucagon Prescribing Information. Lilly USA, LLC. Indianapolis, IN. January 2021.
3. Gvoke Prescribing Information. Xeris Pharmaceuticals, Inc. Chicago IL. December 2023.

Prior Authorization Guideline

Guideline ID	GL-233234
Guideline Name	Emflaza (deflazacort) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	4/26/2017
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Emflaza (deflazacort)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

2 . Criteria

Product Name:Brand Emflaza, generic deflazacort	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMFLAZA	DEFLAZACORT TAB 6 MG	22100017000340	Brand
EMFLAZA	DEFLAZACORT TAB 18 MG	22100017000350	Brand
EMFLAZA	DEFLAZACORT TAB 30 MG	22100017000360	Brand
EMFLAZA	DEFLAZACORT TAB 36 MG	22100017000365	Brand
EMFLAZA	DEFLAZACORT SUSP 22.75 MG/ML	22100017001830	Brand
DEFLAZACORT	DEFLAZACORT TAB 6 MG	22100017000340	Generic
DEFLAZACORT	DEFLAZACORT TAB 18 MG	22100017000350	Generic
DEFLAZACORT	DEFLAZACORT TAB 30 MG	22100017000360	Generic
DEFLAZACORT	DEFLAZACORT TAB 36 MG	22100017000365	Generic
DEFLAZACORT	DEFLAZACORT SUSP 22.75 MG/ML	22100017001830	Generic

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Patient has received genetic testing for a mutation of the dystrophin gene [A, 2]

AND

3 - One of the following [A, 2]:

3.1 Documentation of a confirmed mutation of the dystrophin gene

OR

3.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

4 - Patient is 2 years of age or older

AND

5 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

6 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

AND

7 - Patient has had a trial and failure or intolerance to prednisone or prednisolone given at a dose of 0.75 mg/kg/day or 10 mg/kg/weekend [B, 3-5]

AND

8 - One of the following:

8.1 Trial and intolerance to generic deflazacort tablet (Applies to Brand Emflaza tablet only)

OR

8.2 Trial and intolerance to generic deflazacort suspension (Applies to Brand Emflaza oral suspension only)

Product Name:Brand Emflaza, generic deflazacort	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMFLAZA	DEFLAZACORT TAB 6 MG	22100017000340	Brand
EMFLAZA	DEFLAZACORT TAB 18 MG	22100017000350	Brand
EMFLAZA	DEFLAZACORT TAB 30 MG	22100017000360	Brand
EMFLAZA	DEFLAZACORT TAB 36 MG	22100017000365	Brand
EMFLAZA	DEFLAZACORT SUSP 22.75 MG/ML	22100017001830	Brand
DEFLAZACORT	DEFLAZACORT TAB 6 MG	22100017000340	Generic
DEFLAZACORT	DEFLAZACORT TAB 18 MG	22100017000350	Generic
DEFLAZACORT	DEFLAZACORT TAB 30 MG	22100017000360	Generic
DEFLAZACORT	DEFLAZACORT TAB 36 MG	22100017000365	Generic
DEFLAZACORT	DEFLAZACORT SUSP 22.75 MG/ML	22100017001830	Generic

Approval Criteria

1 - Patient has experienced a benefit from therapy (e.g., improvement or preservation of muscle strength)

AND

2 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

AND

3 - One of the following:

3.1 Trial and intolerance to generic deflazacort tablet (Applies to Brand Emflaza tablet only)

OR

3.2 Trial and intolerance to generic deflazacort suspension (Applies to Brand Emflaza oral suspension only)

Product Name:Brand Emflaza, generic deflazacort tablet	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EMFLAZA	DEFLAZACORT TAB 6 MG	22100017000340	Brand
EMFLAZA	DEFLAZACORT TAB 18 MG	22100017000350	Brand
EMFLAZA	DEFLAZACORT TAB 30 MG	22100017000360	Brand
EMFLAZA	DEFLAZACORT TAB 36 MG	22100017000365	Brand
EMFLAZA	DEFLAZACORT SUSP 22.75 MG/ML	22100017001830	Brand
DEFLAZACORT	DEFLAZACORT TAB 6 MG	22100017000340	Generic
DEFLAZACORT	DEFLAZACORT TAB 18 MG	22100017000350	Generic
DEFLAZACORT	DEFLAZACORT TAB 30 MG	22100017000360	Generic
DEFLAZACORT	DEFLAZACORT TAB 36 MG	22100017000365	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) confirming diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Patient has received genetic testing for a mutation of the dystrophin gene [A, 2]

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) confirming one of the following [A, 2]:

3.1 Documentation of a confirmed mutation of the dystrophin gene

OR

3.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

4 - Patient is 2 years of age or older

AND

5 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

6 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

AND

7 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to prednisone or prednisolone given at a dose of 0.75 mg/kg/day or 10 mg/kg/weekend [B, 3-5]

AND

8 - Both of the following (Applies to Brand Emflaza suspension only):

8.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to generic deflazacort suspension

AND

8.2 Submission of medical records (e.g., chart notes) confirming generic deflazacort suspension has not been effective AND valid clinical rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when generic deflazacort suspension has not been shown to be effective despite having the same active ingredient

3 . Endnotes

A. Genetic testing after a positive biopsy diagnosis of Duchenne muscular dystrophy (DMD) is mandatory [2]. However a muscle biopsy is not necessary if a positive genetic diagnosis is confirmed first. In rare cases, when a genetic test has been done but no mutation has been found, a muscle biopsy is the next necessary step for patients who have increased creatine kinase concentrations and symptoms consistent with DMD.
B. Prednisone 0.75 mg/kg/d should be considered the optimal prednisone dose in DMD. Over 12 months, prednisone 10 mg/kg/weekend is equally effective, although long term outcomes of this alternative regimens are unknown [3].

4 . References

1. Emflaza Prescribing Information. PTC Therapeutics, Inc. South Plainfield, NJ. June 2021.
2. Bushby K, Finkel R, Birnkrant DJ, et al; DMD Care Considerations Working Group. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol. 2010;9(1):77-93.
3. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(5):465-72.
4. Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. Neurology. 2016 Nov 15;87(20):2123-2131.
5. FDA Center for Drug Evaluation and Research. Medical Review [Application Number 208684Orig1s000, 208685Orig1s000]. FDA Web site. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208684,208685Orig1s000MedR.pdf. Accessed March 4, 2024.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Empaveli (pegcetacoplan)

Prior Authorization Guideline

Guideline ID	GL-228408
Guideline Name	Empaveli (pegcetacoplan)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Empaveli (pegcetacoplan)
Paroxysmal Nocturnal Hemoglobinuria Indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

2 . Criteria

Product Name:Empaveli	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMPAVELI	PEGCETACOPLAN SUBCUTANEOUS SOLN 1080 MG/20ML (54 MG/ML)	85804065002020	Brand

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name:Empaveli	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMPAVELI	PEGCETACOPLAN SUBCUTANEOUS SOLN 1080 MG/20ML (54 MG/ML)	85804065002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions)

3 . References

1. Empaveli Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. February 2024.

2. Per clinical consultation with specialist, June 18, 2021.
3. Kulasekararaj AG., et al. “Ravulizumab (ALXN1210) vs Eculizumab in C5-Inhibitor–Experienced Adult Patients with PNH: the 302 Study.” Blood, vol. 133, no. 6, 2019, pp. 540–549.
4. Hillmen P, et al. “Pegcetacoplan versus Eculizumab in Paroxysmal Nocturnal Hemoglobinuria.” New England Journal of Medicine, vol. 384, no. 11, 2021, pp. 1028–1037.

Prior Authorization Guideline

Guideline ID	GL-228845
Guideline Name	Enbrel (etanercept)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Enbrel (etanercept)
Rheumatoid Arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Enbrel can be initiated in combination with methotrexate (MTX) or used alone. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older. **Psoriatic Arthritis (PsA)** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in adult patients with psoriatic arthritis. Enbrel can be used with or without MTX. Also indicated for the treatment of active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older. **Plaque Psoriasis (PsO)** Indicated for the treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Ankylosing Spondylitis (AS) Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

2 . Criteria

Product Name:Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

Product Name:Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

Product Name:Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name:Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand

ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name:Enbrel	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - One of the following [6]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [7]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Enbrel	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1, 6]:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Enbrel	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [8]

Product Name:Enbrel	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 8]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

3 . References

1. Enbrel Prescribing Information. Amgen. Thousand Oaks, CA. October 2023.

2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
7. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
8. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228410
Guideline Name	Endari (L-glutamine oral powder)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Endari (L-glutamine)
Sickle Cell Disease Indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

2 . Criteria

Product Name:Brand Endari, Generic l-glutamine	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENDARI	GLUTAMINE (SICKLE CELL) POWD PACK 5 GM	82801020003020	Brand
L-GLUTAMINE	GLUTAMINE (SICKLE CELL) POWD PACK 5 GM	82801020003020	Generic

Approval Criteria

1 - Diagnosis of sickle cell disease

AND

2 - Used to reduce acute complications of sickle cell disease

AND

3 - Patient is 5 years of age and older

Product Name:Brand Endari, Generic l-glutamine	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENDARI	GLUTAMINE (SICKLE CELL) POWD PACK 5 GM	82801020003020	Brand
L-GLUTAMINE	GLUTAMINE (SICKLE CELL) POWD PACK 5 GM	82801020003020	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Endari Prescribing Information. Emmaus Medical, Inc. Torrance, CA. October 2020.

Prior Authorization Guideline

Guideline ID	GL-228412
Guideline Name	Enjaymo (sutimlimab-jome)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Enjaymo (sutimlimab-jome)
Cold agglutinin disease Indicated for the treatment of hemolysis in adults with cold agglutinin disease.

2 . Criteria

Product Name:Enjaymo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENJAYMO	SUTIMLIMAB-JOME IV SOLN 1100 MG/22ML (50 MG/ML)	85803085302050	Brand

Approval Criteria

1 - Diagnosis of cold agglutinin disease (CAD) based on ALL of the following: [A, 2, 3]

- Presence of chronic hemolysis (e.g., bilirubin level above the normal reference range, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count)
- Positive polyspecific direct antiglobulin test (DAT)
- Monospecific DAT strongly positive for C3d
- Cold agglutinin titer greater than or equal to 64 measured at 4 degree celsius
- Direct antiglobulin test (DAT) result for Immunoglobulin G (IgG) of 1 plus or less

AND

2 - Patient does not have cold agglutinin syndrome secondary to other factors (e.g., overt hematologic malignancy, primary immunodeficiency, infection, rheumatologic disease, systemic lupus erythematosus or other autoimmune disorders) [A, 1, 3]

AND

3 - Baseline hemoglobin level less than or equal to 10.0 gram per deciliter (g/dL) [3]

AND

4 - One of the following: [B,1, 3]

- Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg
- Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater

AND

5 - Prescribed by or in consultation with a hematologist

Product Name:Enjaymo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENJAYMO	SUTIMLIMAB-JOME IV SOLN 1100 MG/22ML (50 MG/ML)	85803085302050	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ALL of the following: [1, 3]

- The patient has not required any blood transfusions after the first 5 weeks of therapy with Enjaymo
- Hemoglobin level greater than or equal to 12 gram per deciliter (g/dL) or increased greater than or equal to 2 g/dL from baseline

AND

2 - One of the following: [B,1, 3]

- Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg
- Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater

AND

3 - Prescribed by or in consultation with a hematologist

3 . Background

Clinical Practice Guidelines
Weight-Based Dosing

The dosing is 6,500mg or 7,500mg Enjaymo (based on body weight) intravenously over approximately 60 minutes on Day 0, Day 7, and every 14 days thereafter	
Body Weight Range	Dose
39kg to less than 75kg	6,500 mg
75kg or greater	7,500 mg

4 . Endnotes

A. Patients with a confirmed diagnosis of CAD based on chronic hemolysis, polyspecific direct antiglobulin test (DAT), monospecific DAT specific for C3d, cold agglutinin titer ≥64 at 4°C, and IgG DAT ≤1+ and a recent blood transfusion in the 6 months prior to enrollment were administered 6.5 g or 7.5 g Enjaymo (based on body weight). Patients with cold agglutinin syndrome secondary to infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy were excluded. [1]
B. The recommended dosage of Enjaymo for patients with CAD is based on body weight. For patients weighing 39 kg to less than 75 kg, the recommended dose is 6,500 mg and for patients weighing 75 kg or more, the recommended dose is 7,500 mg [1]

5 . References

1. Enjaymo Prescribing Information. Bioverativ USA Inc. Waltham, MA. February 2024.
2. Diagnosing Cold Agglutinin Disease (CAD) available at https://www.understandingcad.com/diagnosing-cold-agglutinin-disease/. Accessed March 8, 2022.
3. A Study to Assess the Efficacy and Safety of BIVV009 (Sutimlimab) in Participants with Primary Cold Agglutinin Disease Who Have a Recent History of Blood Transfusion (Cardinal Study). Available at https://clinicaltrials.gov/ct2/show/NCT03347396. Accessed March 8, 2022.
4. Roth, A., Barcellini, W., et al. Sutimlimab in Cold Agglutinin Disease. N Engl J Med 2021; 384:1323-1334. Available at https://www.nejm.org/doi/10.1056/NEJMoa2027760?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed. Accessed March 8, 2022.

Prior Authorization Guideline

Guideline ID	GL-233198
Guideline Name	Enspryng (satralizumab-mwge)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/21/2020
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Enspryng (satralizumab-mwge)
Neuromyelitis Optica Spectrum Disorder (NMOSD) Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name:Enspryng	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENSPRYNG	SATRALIZUMAB-MWGE SUBCUTANEOUS SOLN PREF SYRINGE 120 MG/ML	9940507040E520	Brand

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Ophthalmologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to rituximab

OR

4.2 For continuation of prior Enspryng therapy

Product Name:Enspryng	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENSPRYNG	SATRALIZUMAB-MWGE SUBCUTANEOUS SOLN PREF SYRINGE 120 MG/ML	9940507040E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Enspryng Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2022.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-229080
Guideline Name	Entyvio (vedolizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Entyvio IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	14 Weeks [1, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENTYVIO	VEDOLIZUMAB FOR IV SOLUTION 300 MG	52503080002120	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [2, 3]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [2, 3]:

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- One formulary adalimumab product*
- One formulary ustekinumab product*
- Skyrizi (risankizumab-rzaa)
- Rinvoq (upadacitinib)

OR

4.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with a gastroenterologist

Notes	* For review process only: Refer to the table in the Background section for carrier-specific formulary products

Product Name:Entyvio SC	
Diagnosis	Crohn's Disease (CD)
Approval Length	14 Weeks [1, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENTYVIO	VEDOLIZUMAB SOLN PEN-INJECTOR 108 MG/0.68ML	52503080000D520	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following:

2.1 Will be used as a maintenance dose following two doses of Entyvio IV* for induction

OR

2.2 Patient is currently established on Entyvio IV*

AND

3 - Prescribed by or in consultation with a gastroenterologist

Notes	* This product will require prior authorization

Product Name:Entyvio IV & SC	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENTYVIO	VEDOLIZUMAB FOR IV SOLUTION 300 MG	52503080002120	Brand
ENTYVIO	VEDOLIZUMAB SOLN PEN-INJECTOR 108 MG/0.68ML	5250308000D520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Product Name:Entyvio IV	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	14 Weeks [1, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENTYVIO	VEDOLIZUMAB FOR IV SOLUTION 300 MG	52503080002120	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [4, 5]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [4, 5]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following:

- One formulary adalimumab product*
- Simponi (golimumab)
- One formulary ustekinumab product*
- Omvoh (mirikizumab-mrkz)
- Skyrizi (risankizumab-rzaa)
- Tremfya (guselkumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with a gastroenterologist

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name:Entyvio SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	14 Weeks [1, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENTYVIO	VEDOLIZUMAB SOLN PEN-INJECTOR 108 MG/0.68ML	52503080000D520	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

2.1 Will be used as a maintenance dose following two doses of Entyvio IV* for induction

OR

2.2 Patient is currently established on Entyvio IV*

AND

3 - Prescribed by or in consultation with a gastroenterologist

Notes	* This product will require prior authorization

Product Name:Entyvio IV & SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENTYVIO	VEDOLIZUMAB FOR IV SOLUTION 300 MG	52503080002120	Brand
ENTYVIO	VEDOLIZUMAB SOLN PEN-INJECTOR 108 MG/0.68ML	5250308000D520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4, 5]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

2 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products **Adalimumab-adaz** **Hyrimoz**

Hadlima

Adalimumab-fkjp

Formulary Ustekinumab Products

Formulary Ustekinumab Products
Stelara (ustekinumab)

3 . Endnotes

A. Entyvio should be discontinued in patients who do not show evidence of therapeutic benefit by week 14. [1]

4 . References

1. Entyvio Prescribing Information. Takeda Pharmaceuticals of America, Inc. Deerfield, IL. April 2024.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn’s disease in adults. Am J Gastroenterol. 2018;113:481-517.
3. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
5. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

5 . Revision History

Date	Notes
12/20/2024	New program

Eohilia (budesonide)

Prior Authorization Guideline

Guideline ID	GL-228644
Guideline Name	Eohilia (budesonide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Eohilia (budesonide)
Eosinophilic Esophagitis (EoE) Indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE). Limitations of Use EOHILIA has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks.

2 . Criteria

Product Name:Eohilia	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 Weeks [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EOHILIA	BUDESONIDE ORAL SUSPENSION 2 MG/10ML	22100012001820	Brand

Approval Criteria

1 - Diagnosis of eosinophilic esophagitis (EoE)

AND

2 - Patient has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, heartburn, abdominal pain)

AND

3 - Patient has at least 15 intraepithelial eosinophils per high power field (HPF)

AND

4 - Other causes of esophageal eosinophilia have been excluded

AND

5 - Patient is 11 years of age or older

AND

6 - Trial and failure (of a minimum 8-week duration), contraindication, or intolerance to a proton pump inhibitor (e.g., pantoprazole, omeprazole)

AND

7 - Trial and failure (of a minimum 8-week duration), or intolerance to a topical (esophageal) corticosteroid (e.g., budesonide, fluticasone)

AND

8 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Gastroenterologist

3 . Endnotes

A. EOHILIA has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks (1)

4 . References

1. Eohilia Prescribing Information. Takeda Pharmaceuticals America Inc. Lexington, MA 02421. February 2024.
2. Study Details | A Study in Adolescents and Adults With Eosinophilic Esophagitis (EoE) Measuring Histologic Response and Determine if Reduction in Dysphagia is Achieved | ClinicalTrials.gov https://clinicaltrials.gov/study/NCT02605837. Accessed 8 March, 2024.
3. Gonsalves NP, Aceves SS. Diagnosis and treatment of eosinophilic esophagitis. J Allergy Clin Immunol. 2020;145(1):1-7.
4. Hirano I, Chan ES, Rank MA, et al. AGA Institute and the Joint Task Force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis. Gastroenterology. 2020;158:1776-86.
5. Dellon ES, Khoury P, Muir AB, et al. A clinical severity index for eosinophilic esophagitis: development, consensus, and future directions. Gastroenterology. 2022;1-18.

Prior Authorization Guideline

Guideline ID	GL-228847
Guideline Name	Epclusa (sofosbuvir/velpatasvir) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Epclusa (sofosbuvir and velpatasvir)
Chronic Hepatitis C (CHC) Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis, and with decompensated cirrhosis for use in combination with ribavirin.

2 . Criteria

Product Name:Epclusa*	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6
Approval Length	12 Week(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 200-50 MG	12359902650320	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 150-37.5 MG	12359902653020	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 200-50 MG	12359902653030	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes	*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name:Brand sofosbuvir/velpatasvir

Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 4, 5, or 6
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

5.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 4, 5, or 6
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2, 3
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2, 3
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does not have decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Epclusa*	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 200-50 MG	12359902650320	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 150-37.5 MG	12359902653020	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 200-50 MG	12359902653030	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes	*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Trial and failure or intolerance to Brand Epclusa

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Brand Epclusa

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Epclusa*

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 200-50 MG	12359902650320	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 150-37.5 MG	12359902653020	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 200-50 MG	12359902653030	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes	*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - One of the following:

6.1 Trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - One of the following:

6.1 Trial and failure or intolerance to Brand Epclusa

OR

6.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name:Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Brand Epclusa

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

1. Epclusa Prescribing Information. Gilead Science, Inc. Foster City, CA. April 2022.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228850
Guideline Name	Epidiolex (cannabidiol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Epidiolex (cannabidiol oral solution)
Lennox-Gastaut syndrome (LGS) Indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 1 year of age and older. **Dravet syndrome (DS)** Indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 1 year of age and older. **Tuberous sclerosis complex (TSC)** Indicated for the treatment of seizures associated with tuberous sclerosis complex (TSC) in patients 1 year of age and older.

2 . Criteria

Product Name:Epidiolex

Diagnosis	Lennox-Gastaut syndrome (LGS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPIDIOLEX	CANNABIDIOL SOLN 100 MG/ML	72600017002020	Brand

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

2 - Trial of, contraindication, or intolerance to TWO formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate) [2, A-B]

AND

3 - Patient is 1 year of age or older

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Epidiolex	
Diagnosis	Dravet syndrome (DS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

EPIDIOLEX	CANNABIDIOL SOLN 100 MG/ML	72600017002020	Brand

Approval Criteria

1 - Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2 - Patient is 1 year of age or older

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Epidiolex	
Diagnosis	Tuberous sclerosis complex
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPIDIOLEX	CANNABIDIOL SOLN 100 MG/ML	72600017002020	Brand

Approval Criteria

1 - Diagnosis of seizures associated with tuberous sclerosis complex (TSC)

AND

2 - Patient is 1 year of age or older

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Epidiolex	
Diagnosis	Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), Tuberous sclerosis complex (TSC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPIDIOLEX	CANNABIDIOL SOLN 100 MG/ML	72600017002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. The effectiveness of Epidiolex for the treatment of seizures associated with LGS was established in two randomized, double-blind, placebo-controlled trials in patients aged 2 to 55 years. In study 2, 225 patients underwent randomization, of whom 76 were assigned to the 20-mg cannabidiol group, 73 to the 10-mg cannabidiol group, and 76 to the placebo group; Patients in each group had previously received a median of 6 antiepileptic drugs (range, 0 to 22), but the drugs had failed to control the seizures; the patients were receiving a median of 3 antiepileptic drugs concomitantly at the time of trial entry. [3]

B. To improve patient care and facilitate clinical research, the International League Against Epilepsy (ILAE) appointed a Task Force to formulate a consensus definition of drug resistant epilepsy. The following definition was formulated: Drug resistant epilepsy may be defined as failure of adequate trials of two tolerated and appropriately chosen and used antiepileptic drug (AED) schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom. [4]

4 . References

1. Epidiolex Prescribing Information. Greenwich Biosciences, Inc. Carlsbad, CA. April 2022.
2. Per clinical consult with neurologist, July 30, 2018.
3. Devinsky O, Patel AD, Cross JH, et al. Effect of cannabidiol on drop seizures in the Lennox-Gastaut syndrome. N Engl J Med. 2018 May 17;378(20):1888-1897.
4. Kwan P, Arzimanoglou A, Berg AT, et al. Definition of drug resistant epilepsy: consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. Epilepsia. 2010 Jun;51(6):1069-77.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228646
Guideline Name	Epinephrine Injection Products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: EpiPen (epinephrine injection), EpiPen Jr. (epinephrine injection), epinephrine injection
Allergic reactions Indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

2 . Criteria

Product Name:Brand EpiPen, Brand EpiPen Jr.	
Approval Length	6 month(s)

Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
EPIPEN-JR 2-PAK	EPINEPHRINE SOLUTION AUTO-INJECTOR 0.15 MG/0.3ML (1:2000)	3890004000D520	Brand
EPIPEN 2-PAK	EPINEPHRINE SOLUTION AUTO-INJECTOR 0.3 MG/0.3ML (1:1000)	3890004000D540	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (within the past 180 days) or intolerance to generic epinephrine

3 . References

1. EpiPen prescribing information. Mylan Specialty L.P. Morgantown, WV. February 2023.
2. EpiPen Jr prescribing information. Mylan Specialty L.P. Morgantown, WV. February 2023.

Prior Authorization Guideline

Guideline ID	GL-228413
Guideline Name	Erectile Dysfunction Medications
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cialis (tadalafil)
Benign Prostatic Hyperplasia (BPH) and Erectile Dysfunction (ED) Indicated for the treatment of erectile dysfunction (ED), the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) and for the treatment of erectile dysfunction (ED) and the signs and symptoms of BPH (ED/BPH). Limitation of use: If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of Cialis decreases from 4 weeks until 26 weeks, and the incremental benefit of Cialis beyond 26 weeks is unknown.

2 . Criteria

Product Name:Brand Cialis 2.5 mg, Brand Cialis 5 mg, Generic tadalafil 2.5 mg, or Generic tadalafil 5 mg

Approval Length	12 month(s)
Guideline Type	Non-Formulary / Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIALIS	TADALAFIL TAB 2.5 MG	40304080000302	Brand
CIALIS	TADALAFIL TAB 5 MG	40304080000305	Brand
TADALAFIL	TADALAFIL TAB 2.5 MG	40304080000302	Generic
TADALAFIL	TADALAFIL TAB 5 MG	40304080000305	Generic

Approval Criteria

1 - Diagnosis of benign prostatic hyperplasia (BPH) [A]

AND

2 - The request is for one of the following: [B]

- Cialis (tadalafil) 2.5 mg
- Cialis (tadalafil) 5 mg

3 . Endnotes

A. Cialis (tadalafil) is the only impotence agent approved by the FDA for the treatment of benign prostatic hyperplasia (BPH). The medication is available as a 2.5 mg, 5 mg, 10 mg, and 20 mg tablet; however, only the 2.5 mg and 5 mg doses are used for BPH. [1]
B. For BPH: The recommended dose is 5 mg once daily; however, this dose may be reduced to 2.5 mg once daily for patients with renal impairment or drug interactions (i.e., use with CYP3A4 inhibitors). [1]

4 . References

1. Cialis prescribing information. Eli Lilly and Company. Indianapolis, IN. April 2023.

Prior Authorization Guideline

Guideline ID	GL-228852
Guideline Name	Ergot Alkaloids
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: D.H.E. 45 (dihydroergotamine mesylate) injection
Migraine Indicated for the acute treatment of migraine headaches with or without aura. **Cluster Headache** Indicated for the acute treatment of cluster headache episodes.
Drug Name: Migranal (dihydroergotamine mesylate) nasal spray
Migraine Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.
Drug Name: Cafergot (ergotamine tartrate and caffeine) tablet, Ergomar (ergotamine tartrate) sublingual tablet, Migergot (ergotamine tartrate and caffeine) suppository
Headache Indicated as therapy to abort or prevent vascular headache, e.g., migraine, migraine variants, or so-called “histaminic cephalalgia”.
Drug Name: Trudhesa (dihydroergotamine mesylate) nasal spray

Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: - Not indicated for the preventive treatment of migraine. - Not indicated for the management of hemiplegic or basilar migraine.

2 . Criteria

Product Name:Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, or Trudhesa nasal spray

Diagnosis	Migraines
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Generic
MIGRANAL	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Brand
D.H.E. 45	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Brand
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Generic
MIGERGOT	ERGOTAMINE W/ CAFFEINE SUPPOS 2-100 MG	67991002105220	Brand
ERGOTAMINE TARTRATE/CAFFEINE	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Generic
CAFERGOT	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Brand
ERGOMAR	ERGOTAMINE TARTRATE SL TAB 2 MG	67000020100705	Brand
TRUDHESA	DIHYDROERGOTAMINE MESYLATE HFA NASAL AEROSOL 0.725 MG/ACT	67000030113420	Brand

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [A]

AND

4 - One of the following: [3]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [B, 4]

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication
- Generic lisinopril unless there is a contraindication or intolerance to this medication

Product Name:Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, or Trudhesa nasal spray	
Diagnosis	Migraines
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Generic
MIGRANAL	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Brand
D.H.E. 45	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Brand
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Generic
MIGERGOT	ERGOTAMINE W/ CAFFEINE SUPPOS 2-100 MG	67991002105220	Brand
ERGOTAMINE TARTRATE/CAFFEINE	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Generic
CAFERGOT	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Brand
ERGOMAR	ERGOTAMINE TARTRATE SL TAB 2 MG	67000020100705	Brand
TRUDHESA	DIHYDROERGOTAMINE MESYLATE HFA NASAL AEROSOL 0.725 MG/ACT	67000030113420	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

Product Name:Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, or Migergot suppository	
Diagnosis	Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
D.H.E. 45	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Brand
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Generic

MIGERGOT	ERGOTAMINE W/ CAFFEINE SUPPOS 2-100 MG	67991002105220	Brand
ERGOTAMINE TARTRATE/CAFFEINE	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Generic
CAFERGOT	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Brand
ERGOMAR	ERGOTAMINE TARTRATE SL TAB 2 MG	67000020100705	Brand

Approval Criteria

1 - Diagnosis of cluster headache

AND

2 - Patient is 18 years of age or older [A]

AND

3 - Trial and failure, contraindication, or intolerance to sumatriptan injection [5]

Product Name:Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, or Migergot suppository	
Diagnosis	Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
D.H.E. 45	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Brand
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Generic
MIGERGOT	ERGOTAMINE W/ CAFFEINE SUPPOS 2-100 MG	67991002105220	Brand
ERGOTAMINE TARTRATE/CAFFEINE	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Generic

CAFERGOT	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Brand
ERGOMAR	ERGOTAMINE TARTRATE SL TAB 2 MG	67000020100705	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

3 . Endnotes

A. The safety and effectiveness in pediatric patients has not been established. [1, 2]
B. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan. [3, 4]

4 . References

1. D.H.E. 45 Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. April 2022.
2. Migranal Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2022.
3. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.
4. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26.
5. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. Headache. 2016 Jul;56(7):1093-106.
6. Cafergot Prescribing Information. Sandoz Inc. Princeton, NJ. May 2018
7. Ergomar Prescribing Information. TerSera Therapeutics LLC. Deerfield, IL. February 2020.
8. Migergot Prescribing Information. Cosette Pharmaceuticals, Inc.. South Plainfield, NJ. June 2020.
9. Trudhesa Prescribing Information. Impel Pharmaceuticals Inc. Seattle, WA. August 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228854
Guideline Name	Erivedge (vismodegib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Erivedge (vismodegib)
Basal cell carcinoma Indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

2 . Criteria

Product Name:Erivedge	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ERIVEDGE	VISMODEGIB CAP 150 MG	21370070000120	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of metastatic basal cell carcinoma

OR

1.2 Both of the following:

1.2.1 Diagnosis of locally advanced basal cell carcinoma

AND

1.2.2 One of the following:

- Disease recurred following surgery
- Patient is not a candidate for both surgery and radiation

Product Name:Erivedge	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ERIVEDGE	VISMODEGIB CAP 150 MG	21370070000120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Erivedge Prescribing Information. Genentech USA Inc. South San Francisco, CA. August 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 4, 2020..

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228415
Guideline Name	Erleada (apalutamide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Erleada (apalutamide)
Non-metastatic castration-resistant prostate cancer Indicated for the treatment of patients with non-metastatic, castration-resistant prostate cancer (NM-CRPC).
Drug Name: Erleada (apalutamide)
Metastatic castration-sensitive prostate cancer Indicated for the treatment of patients with metastatic, castration-sensitive prostate cancer (M-CSPC).

2 . Criteria

Product Name:Erleada	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ERLEADA	APALUTAMIDE TAB 60 MG	21402410000320	Brand
ERLEADA	APALUTAMIDE TAB 240 MG	21402410000360	Brand

Approval Criteria

1 - Diagnosis of prostate cancer

Product Name:Erleada	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ERLEADA	APALUTAMIDE TAB 60 MG	21402410000320	Brand
ERLEADA	APALUTAMIDE TAB 240 MG	21402410000360	Brand

Approval Criteria

1 - Patient does not show evidence of disease progression while on therapy

3 . References

1. Erleada prescribing information. Janssen Ortho LLC. Gurabo, PR. December 2023.

Prior Authorization Guideline

Guideline ID	GL-233237
Guideline Name	Erythropoietic Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	3/17/2000
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Aranesp (darbepoetin alfa)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis. **Anemia Due to Chemotherapy in Patients with Cancer** Indicated for treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Aranesp has not been shown to improve quality of life, fatigue, or patient well-being. Aranesp is not indicated for use: (1) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; and (4) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia.

Off Label Uses: Anemia in patients with Myelodysplastic Syndrome (MDS) Has been used for the treatment of anemia in patients with MDS. [20]

Drug Name: Epogen (epoetin alfa), Procrit (epoetin alfa), and Retacrit (epoetin alfa-epbx)

Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.

Anemia Due to Zidovudine in Patients with HIV-infection Indicated for the treatment of anemia due to zidovudine administered at less than or equal to 4200 mg/week in patients with HIV-infection with endogenous serum erythropoietin levels of less than or equal to 500 mUnits/mL.

Anemia Due to Chemotherapy in Patients with Cancer Indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and upon initiation, there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use: (1) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; (4) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia.

Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery Indicated to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin greater than 10 to less than or equal to 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood preoperatively. Limitations of Use: Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use: (1) In patients scheduled for surgery who are willing to donate autologous blood; (2) In patients undergoing cardiac or vascular surgery; (3) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia.

Off Label Uses: Anemia associated with HIV infection Have been used for the treatment of anemia associated with HIV infection in patients not receiving zidovudine. [5]

Anemia in Hepatitis C virus (HCV) infected patients due to combination therapy of ribavirin and interferon or peg-interferon Have been used for the treatment of anemia in patients with hepatitis C virus (HCV) infection who are being treated with the combination of ribavirin and interferon or peginterferon alfa. [20]

Anemia in patients with Myelodysplastic Syndrome (MDS) Have been used for the treatment of anemia in patients with MDS. [5, 20]

Drug Name: Mircera (methoxy polyethylene glycol-epoetin beta)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia associated with chronic kidney disease (CKD) in: (1) adult patients on dialysis and adult patients not on dialysis; (2) pediatric patients 3 months to 17 years of age on dialysis or not on dialysis, who are converting from another ESA after their hemoglobin level was stabilized with an ESA. Limitations of use: Mircera is not indicated and is not recommended: (1) In the treatment of anemia due to cancer chemotherapy; or (2) As a substitute for RBC transfusions in patients who require immediate correction of anemia. Mircera has not been shown to improve symptoms, physical functioning, or health-related quality of life.

2 . Criteria

Product Name:Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 10 MCG/0.4ML	8240101510E510	Brand

ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 25 MCG/0.42ML	8240101510E528	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 40 MCG/0.4ML	8240101510E543	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 60 MCG/0.3ML	8240101510E552	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 100 MCG/0.5ML	8240101510E560	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 150 MCG/0.3ML	8240101510E575	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 200 MCG/0.4ML	8240101510E582	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 300 MCG/0.6ML	8240101510E588	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 500 MCG/ML	8240101510E590	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 25 MCG/ML	82401015102010	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 40 MCG/ML	82401015102020	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 60 MCG/ML	82401015102030	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 100 MCG/ML	82401015102040	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 200 MCG/ML	82401015102060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Adequate iron stores confirmed by both of the following: [A, J]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [1-3, 9, 13-17, 29, 33, B]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL

AND

4 - One of the following: [1-3, 33, L]

4.1 Patient is on dialysis

OR

4.2 All of the following:

4.2.1 Patient is NOT on dialysis

AND

4.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

4.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

AND

5 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Product Name:Mircera	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 50 MCG/0.3ML	8240104010E515	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 75 MCG/0.3ML	8240104010E520	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 100 MCG/0.3ML	8240104010E525	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 200 MCG/0.3ML	8240104010E545	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 30 MCG/0.3ML	8240104010E510	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 150 MCG/0.3ML	8240104010E535	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 120 MCG/0.3ML	8240104010E530	Brand

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Adequate iron stores confirmed by both of the following: [A, J]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

3 - One of the following:

3.1 All of the following:

3.1.1 Patient is 18 years of age or older

AND

3.1.2 Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [9, 13-17, 29, 31, B]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL

AND

3.1.3 One of the following: [31]

3.1.3.1 Patient is on dialysis

OR

3.1.3.2 All of the following:

3.1.3.2.1 Patient is NOT on dialysis

AND

3.1.3.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

3.1.3.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

OR

3.2 All of the following:

3.2.1 Patient is between 3 months and 17 years of age

AND

3.2.2 Patient's hemoglobin level has been stabilized by treatment with another erythropoietin stimulating agent (ESA) (e.g., Aranesp, Retacrit)

AND

3.2.3 Patient is converting to Mircera from another ESA (e.g., Aranesp, Retacrit)

AND

4 - History of use or unavailability of both of the following: [O]

- Aranesp
- Retacrit or Procrit

Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 10 MCG/0.4ML	8240101510E510	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 25 MCG/0.42ML	8240101510E528	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 40 MCG/0.4ML	8240101510E543	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 60 MCG/0.3ML	8240101510E552	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 100 MCG/0.5ML	8240101510E560	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 150 MCG/0.3ML	8240101510E575	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 200 MCG/0.4ML	8240101510E582	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 300 MCG/0.6ML	8240101510E588	Brand

ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 500 MCG/ML	8240101510E590	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 25 MCG/ML	82401015102010	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 40 MCG/ML	82401015102020	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 60 MCG/ML	82401015102030	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 100 MCG/ML	82401015102040	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 200 MCG/ML	82401015102060	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 50 MCG/0.3ML	8240104010E515	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 75 MCG/0.3ML	8240104010E520	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 100 MCG/0.3ML	8240104010E525	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 200 MCG/0.3ML	8240104010E545	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 30 MCG/0.3ML	8240104010E510	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 150 MCG/0.3ML	8240104010E535	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 120 MCG/0.3ML	8240104010E530	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - One of the following:

2.1 Both of the following:

- Patient is on dialysis
- Most recent or average Hct over 3 months is 33% or less (Hgb 11 g/dL or less)

OR

2.2 Both of the following:

- Patient is not on dialysis
- Most recent or average (avg) Hct over 3 mo is 30% or less (Hgb 10 g/dL or less)

OR

2.3 Both of the following:

- Request is for a pediatric patient
- Most recent or average Hct over 3 mo is 36% or less (Hgb 12 g/dL or less)

AND

3 - One of the following: [1-3, 31, 33]

3.1 Decrease in the need for blood transfusion

OR

3.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

AND

4 - Adequate iron stores confirmed by both of the following: [A, J]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name:Epogen, Procrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [A, J]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

3 - Submission of medical records (e.g., chart notes) confirming anemia as defined by one of the following laboratory values collected within 30 days of the request: [1-3, 9, 13-17, 29, 33, B]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL

AND

4 - One of the following: [1-3, 33, L]

4.1 Patient is on dialysis

OR

4.2 All of the following:

4.2.1 Patient is NOT on dialysis

AND

4.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

4.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Product Name:Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand

RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Adequate iron stores confirmed by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request:

- Hemoglobin (Hgb) less than 12 g/dL [11, 25-28, K]
- Hematocrit (Hct) less than 36%

AND

3 - Serum erythropoietin level less than or equal to 500 mU/mL [2-3, 24, 26, 33]

AND

4 - One of the following:

- Patient is receiving zidovudine therapy [2-3, 33]
- Diagnosis of HIV infection [off-label] [5, 11, 24-28]

AND

5 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Product Name:Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Verification of anemia as defined by one of the following: [2, 3, 33]

- Most recent or average hematocrit (Hct) over a 3-month period was below 36%
- Most recent or average hemoglobin (Hgb) over a 3-month period was below 12 g/dL

AND

2 - One of the following: [2, 3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

Product Name:Epogen, Procrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

2 - Submission of medical records (e.g., chart notes) confirming anemia as defined by one of the following laboratory values collected within 30 days of the request:

- Hemoglobin (Hgb) less than 12 g/dL [11, 25-28, K]
- Hematocrit (Hct) less than 36%

AND

3 - Submission of medical records (e.g., chart notes) confirming serum erythropoietin level less than or equal to 500 mU/mL [2-3, 24, 26, 33]

AND

4 - One of the following:

- Patient is receiving zidovudine therapy [2-3, 33]
- Diagnosis of HIV infection [off-label] [5, 11, 24-28]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Product Name:Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic

PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 10 MCG/0.4ML	8240101510E510	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 25 MCG/0.42ML	8240101510E528	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 40 MCG/0.4ML	8240101510E543	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 60 MCG/0.3ML	8240101510E552	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 100 MCG/0.5ML	8240101510E560	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 150 MCG/0.3ML	8240101510E575	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 200 MCG/0.4ML	8240101510E582	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 300 MCG/0.6ML	8240101510E588	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 500 MCG/ML	8240101510E590	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 25 MCG/ML	82401015102010	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 40 MCG/ML	82401015102020	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 60 MCG/ML	82401015102030	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 100 MCG/ML	82401015102040	Brand

ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 200 MCG/ML	82401015102060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Verification that other causes of anemia have been ruled out [1-3, 33, M]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL [N]

AND

3 - Adequate iron stores confirmed by both of the following: [1-3, 8, 33, G]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Verification that the cancer is a non-myeloid malignancy [1-3, 33, F]

AND

5 - Patient is receiving chemotherapy [1-3, 33, D]

AND

6 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Product Name:Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 10 MCG/0.4ML	8240101510E510	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 25 MCG/0.42ML	8240101510E528	Brand

ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 40 MCG/0.4ML	8240101510E543	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 60 MCG/0.3ML	8240101510E552	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 100 MCG/0.5ML	8240101510E560	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 150 MCG/0.3ML	8240101510E575	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 200 MCG/0.4ML	8240101510E582	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 300 MCG/0.6ML	8240101510E588	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 500 MCG/ML	8240101510E590	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 25 MCG/ML	82401015102010	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 40 MCG/ML	82401015102020	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 60 MCG/ML	82401015102030	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 100 MCG/ML	82401015102040	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 200 MCG/ML	82401015102060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hemoglobin (Hgb) less than 10 g/dL
- Hematocrit (Hct) less than 30% [10, 18-19]

AND

2 - One of the following: [1-3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

AND

3 - Patient is receiving chemotherapy [D]

Product Name:Epogen, Procrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic

PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand

Approval Criteria

1 - Verification that other causes of anemia have been ruled out [1-3, 33, M]

AND

2 - Submission of medical records (e.g., chart notes) confirming anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL [N]

AND

3 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [1-3, 8, 33, G]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Verification that the cancer is a non-myeloid malignancy [1-3, 33, F]

AND

5 - Patient is receiving chemotherapy [1-3, 33, D]

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Product Name:Epogen, Procrit, or Retacrit	
Diagnosis	Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery
Approval Length	1 month [2]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery

AND

2 - Hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL

AND

3 - Patient is at high risk for perioperative transfusions

AND

4 - Patient is unwilling or unable to donate autologous blood pre-operatively

AND

5 - Adequate iron stores confirmed by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

6 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Product Name:Epogen, Procrit	
Diagnosis	Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery
Approval Length	1 month [2]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic

EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand

Approval Criteria

1 - Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery

AND

2 - Submission of medical records (e.g., chart notes) confirming hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL

AND

3 - Patient is at high risk for perioperative transfusions

AND

4 - Patient is unwilling or unable to donate autologous blood pre-operatively

AND

5 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Product Name:Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label] [4-6, 20]
Approval Length	3 months [I]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 10 MCG/0.4ML	8240101510E510	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 25 MCG/0.42ML	8240101510E528	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 40 MCG/0.4ML	8240101510E543	Brand

ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 60 MCG/0.3ML	8240101510E552	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 100 MCG/0.5ML	8240101510E560	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 150 MCG/0.3ML	8240101510E575	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 200 MCG/0.4ML	8240101510E582	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 300 MCG/0.6ML	8240101510E588	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 500 MCG/ML	8240101510E590	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 25 MCG/ML	82401015102010	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 40 MCG/ML	82401015102020	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 60 MCG/ML	82401015102030	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 100 MCG/ML	82401015102040	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 200 MCG/ML	82401015102060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Diagnosis of Myelodysplastic Syndrome (MDS) [4]

AND

2 - One of the following: [4]

- Serum erythropoietin level less than or equal to 500 mU/mL
- Diagnosis of transfusion-dependent MDS

AND

3 - Adequate iron stores confirmed by both of the following: [4, A, H]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Product Name:Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic

PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 10 MCG/0.4ML	8240101510E510	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 25 MCG/0.42ML	8240101510E528	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 40 MCG/0.4ML	8240101510E543	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 60 MCG/0.3ML	8240101510E552	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 100 MCG/0.5ML	8240101510E560	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 150 MCG/0.3ML	8240101510E575	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 200 MCG/0.4ML	8240101510E582	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 300 MCG/0.6ML	8240101510E588	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 500 MCG/ML	8240101510E590	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 25 MCG/ML	82401015102010	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 40 MCG/ML	82401015102020	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 60 MCG/ML	82401015102030	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 100 MCG/ML	82401015102040	Brand

ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 200 MCG/ML	82401015102060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Verification of anemia as defined by one of the following: [4, E]

- Most recent or average hematocrit (Hct) over a 3-month period was less than or equal to 36%
- Most recent or average hemoglobin (Hgb) over a 3-month period was less than or equal to 12 g/dL

AND

2 - One of the following: [1-3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1.5 g/dL from pre-treatment level

Product Name:Epogen, Procrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label] [4-6, 20]
Approval Length	3 months [I]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand

Approval Criteria

1 - Diagnosis of Myelodysplastic Syndrome (MDS) [4]

AND

2 - One of the following: [4]

- Diagnosis of transfusion-dependent MDS
- Serum erythropoietin level less than or equal to 500 mU/mL

AND

3 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [4, A, H]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Product Name:Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label] [6]
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Diagnosis of hepatitis C viral (HCV) infection [12, 20]

AND

2 - Adequate iron stores confirmed by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [P]

- Hematocrit (Hct) less than 36%
- Hemoglobin (Hgb) less than 12 g/dL

AND

4 - Verification of both of the following:

4.1 Patient is receiving ribavirin

AND

4.2 Patient is receiving one of the following:

- interferon alfa
- peginterferon alfa

AND

5 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Product Name:Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label]
Approval Length	3 Months or if patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy.
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Verification of anemia as defined by one of the following: [35]

- Most recent or average hematocrit (Hct) over a 3-month period was 36% or less

- Most recent or average hemoglobin (Hgb) over a 3-month period was 12 g/dL or less

AND

2 - One of the following: [2, 3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

Product Name:Epogen, Procrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label] [6]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand

Approval Criteria

1 - Diagnosis of hepatitis C viral (HCV) infection [12, 20]

AND

2 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

3 - Submission of medical records (e.g., chart notes) confirming anemia as defined by one of the following laboratory values collected within 30 days of the request: [P]

- Hematocrit (Hct) less than 36%
- Hemoglobin (Hgb) less than 12 g/dL

AND

4 - Verification of both of the following:

4.1 Patient is receiving ribavirin

AND

4.2 Patient is receiving one of the following:

- interferon alfa
- peginterferon alfa

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Product Name:Aranesp, Epogen, Mircera, Procrit, or Retacrit	
Diagnosis	Other Off-Label Uses
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 10 MCG/0.4ML	8240101510E510	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 25 MCG/0.42ML	8240101510E528	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 40 MCG/0.4ML	8240101510E543	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 60 MCG/0.3ML	8240101510E552	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 100 MCG/0.5ML	8240101510E560	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 150 MCG/0.3ML	8240101510E575	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 200 MCG/0.4ML	8240101510E582	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 300 MCG/0.6ML	8240101510E588	Brand

ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 500 MCG/ML	8240101510E590	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 25 MCG/ML	82401015102010	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 40 MCG/ML	82401015102020	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 60 MCG/ML	82401015102030	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 100 MCG/ML	82401015102040	Brand
ARANESP ALBUMIN FREE	DARBEPOETIN ALFA SOLN INJ 200 MCG/ML	82401015102060	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 50 MCG/0.3ML	8240104010E515	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 75 MCG/0.3ML	8240104010E520	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 100 MCG/0.3ML	8240104010E525	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 200 MCG/0.3ML	8240104010E545	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 30 MCG/0.3ML	8240104010E510	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 150 MCG/0.3ML	8240104010E535	Brand
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 120 MCG/0.3ML	8240104010E530	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand

Approval Criteria

1 - Off-label guideline approval criteria have been met*

AND

2 - Off-label requests other than those listed above for coverage in patients with Hgb greater than 10 g/dL or Hct greater than 30% will not be approved [1-3, 31, 33]

Notes	*Off-label requests will be evaluated on a case-by-case basis by a clinical pharmacist

Product Name:Epogen, Procrit	
Diagnosis	Other Off-Label Uses
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand

Approval Criteria

1 - Off-label guideline approval criteria have been met*

AND

2 - Off-label requests other than those listed above for coverage in patients with Hgb greater than 10 g/dL or Hct greater than 30% will not be approved [1-3, 31, 33]

Notes	*Off-label requests will be evaluated on a case-by-case basis by a clin ical pharmacist

3 . Endnotes

A. Aranesp, Epogen, Mircera, Procrit, and Retacrit Prescribing Information recommend prior and during therapy, the patient's iron stores should be evaluated. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%. The majority of patients with CKD will require supplemental iron during the course of ESA therapy. [1-3, 31, 33]
B. Aranesp, Epogen, Mircera, Procrit, or Retacrit Prescribing Information states that dialysis, and non-dialysis patients with symptomatic anemia considered for therapy should have a Hgb < 10 g/dL. [1-3, 31, 33]
C. ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen. [18]
D. ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure. [1-3, 33]
E. NCCN panel recommends MDS patients aim for a target hemoglobin level of less than or equal to 12 g/dL. [4]
F. The American Cancer Society definition of "non-myeloid malignancy" is any malignancy that is not a myeloid leukemia. Non-myeloid cancers include all types of carcinoma, all types of sarcoma, melanoma, lymphomas, lymphocytic leukemias (ALL and CLL), and multiple myeloma. [30]
G. Absolute iron deficiency is defined as ferritin <30 ng/mL and TSAT <20%. Functional iron deficiency in patients receiving ESAs is defined as ferritin 30-800 ng/mL and TSAT 20%-50%. No iron deficiency is defined as ferritin >800 ng/mL or TSAT greater or equal to 50%. [8]
H. Iron repletion needs to be verified before instituting Epo therapy. [4]
I. Detection of erythroid responses generally occurs within 6 to 8 weeks of treatment. If no response occurs in this time frame, this treatment should be considered a failure and discontinued. [4]
J. Iron stores evaluation is recommended to occur every month during initial erythropoietin treatment in adults with chronic kidney disease or at least every 3 months during stable ESA treatment or in patients with HD-CKD not treated with an erythropoietin. [7]
K. Anemia in HIV patients has been defined as hemoglobin less than 10 g/dL [11, 25-26], hemoglobin less than 11 g/dL [11, 27], or hemoglobin less than 12 g/dL. [17]
L. Although primarily used in patients with ESRD, ESAs such as erythropoietin and darbepoetin alfa also correct the anemia in those with CKD who do not yet require dialysis. [21, 32]
M. Examples of other anemias include: vitamin B12, folate or iron deficiency anemia, hemolysis, or gastrointestinal bleeding.
N. Data from a systematic review by the Agency for Healthcare Research and Quality (AHRQ) determined that delaying ESA treatment until hemoglobin is less than 10 g/dL resulted in fewer thromboembolic events and a reduced mortality. [8]
O. Per consult with hematologist/oncologist, if a patient does not respond to one short-acting ESA, switching to another short-acting agent would not provide any added

benefit; instead, one would increase the dose or perhaps switch to a long-acting agent. [34]

P. Epoetin alfa was effective in maintaining the dose of rivabirin in anemic patients with chronic hepatitis C virus in patients with a baseline hemoglobin of 12 g/dL or less. [20]

4 . References

1. Aranesp prescribing information. Amgen Inc. Thousand Oaks, CA. April 2024.
2. Epogen prescribing information. Amgen Inc. Thousand Oaks, CA. April 2024.
3. Procrit prescribing information. Amgen Inc. Thousand Oaks, CA. April 2024.
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5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228418
Guideline Name	Evenity (romosozumab-aqqg injection)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Evenity (romosozumab-aqqg injection)
Postmenopausal women with osteoporosis at high risk of fracture Indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name:Evenity	
Approval Length	12 Months [A]*
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EVENITY	ROMOSOZUMAB-AQQG INJ SOLN PREFILLED SYRINGE 105 MG/1.17ML	3004486010E520	Brand

Approval Criteria

1 - Diagnosis of postmenopausal osteoporosis or osteopenia

AND

2 - One of the following:

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) [B]

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) [B]

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [C]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Trial of, contraindication, or intolerance to one of the following:

- Forteo (teriparatide)
- Tymlos (abaloparatide)

AND

4 - Treatment duration of Evenity (romosozumab-aqqg) has not exceeded a total of 12 months during the patient's lifetime [A]

Notes	Evenity (romosozumab-aqqg) not to exceed the FDA-recommended tr eatment duration of 12 monthly doses.

	*Evenity will not be approved if the patient has already received 12 m onths of therapy; if the patient has not yet received 12 months of thera py, approval may be granted for the balance of the time remaining.

3 . Endnotes

A. The anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, the duration of Evenity use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered. [1]
B. Antiresorptive agents work by slowing the resorption or breakdown part of the remodeling cycle. Examples of antiresorptive agents include bisphosphonates (alendronate, ibandronate, risedronate, zoledronic acid), Prolia (denosumab), calcitonin, and selective estrogen receptor modulators (raloxifene). [2-4]
C. The WHO FRAX tool is available at https://frax.shef.ac.uk/FRAX/ and incorporates multiple clinical factors that predict fracture risk, largely independent of BMD. [2]

4 . References

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Prior Authorization Guideline

Guideline ID	GL-228648
Guideline Name	Evkeeza (evinacumab-dgnb)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Evkeeza (evinacumab-dgnb)
Homozygous Familial Hypercholesterolemia (HoFH) Indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia (HoFH). **Limitations of Use** The safety and effectiveness of Evkeeza have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH). The effects of Evkeeza on cardiovascular morbidity and mortality have not been determined.

2 . Criteria

Product Name:Evkeeza

Diagnosis	Homozygous Familial Hypercholesterolemia [HoFH]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EVKEEZA	EVINACUMAB-DGNB IV SOLN 345 MG/2.3ML (150 MG/ML)	39392030202020	Brand
EVKEEZA	EVINACUMAB-DGNB IV SOLN 1200 MG/8ML (150 MG/ML)	39392030202040	Brand

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by one of the following: [2]

1.1 Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus

OR

1.2 Both of the following:

1.2.1 Untreated LDL-C greater than 400 mg/dL

AND

1.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia in both parents

AND

2 - Patient is 5 years of age or older

AND

3 - One of the following:

- Patient is currently treated with maximally tolerated statin therapy
- Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
- Patient has a contraindication to all statins

AND

4 - One of the following:

- Patient has been receiving ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy
- Patient has a history of intolerance or contraindication to ezetimibe
- Patient is less than 10 years of age

AND

5 - One of the following:

- Patient has been treated with PCSK9 therapy or did not respond to PCSK9 therapy
- Physician attests that the patient is known to have two LDL-receptor negative alleles (little to no residual function) and therefore would not respond to PCSK9 therapy
- Patient has a history of intolerance or contraindication to PCSK9 therapy
- Patient is less than 10 years of age

AND

6 - Patient will continue other traditional lipid-lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Evkeeza

AND

7 - Dose will not exceed 15 mg/kg of bodyweight infused once every 4 weeks

AND

8 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Hepatologist

Product Name:Evkeeza	
Diagnosis	Homozygous Familial Hypercholesterolemia [HoFH]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EVKEEZA	EVINACUMAB-DGNB IV SOLN 345 MG/2.3ML (150 MG/ML)	39392030202020	Brand
EVKEEZA	EVINACUMAB-DGNB IV SOLN 1200 MG/8ML (150 MG/ML)	39392030202040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to as evidenced by LDL-C reduction from baseline

AND

2 - Patient will continue other traditional lipid-lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Evkeeza

AND

3 - Dose will not exceed 15 mg/kg of bodyweight infused once every 4 weeks

AND

4 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Hepatologist

3 . Endnotes

A. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. Additionally, in the Evkeeza pivotal trial the primary outcome of change in LDL-C was evaluated at 24 weeks. [3]
B. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [3]

4 . References

1. Evkeeza Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. March 2023.
2. Cuchel M, Raal FJ, Hegele RA, Al-Rasadi K, Arca M, Averna M, Bruckert E, Freiberger T, Gaudet D, Harada-Shiba M, Hudgins LC, Kayikcioglu M, Masana L, Parhofer KG, Roeters van Lennep JE, Santos RD, Stroes ESG, Watts GF, Wiegman A, Stock JK, Tokgözoğlu LS, Catapano AL, Ray KK. 2023 Update on European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolaemia: new treatments and clinical guidance. Eur Heart J. 2023 Jul 1;44(25):2277-2291. doi:10.1093/eurheartj/ehad197. PMID: 37130090; PMCID: PMC10314327.
3. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.

Prior Authorization Guideline

Guideline ID	GL-229138
Guideline Name	Evrysdi (risdiplam)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/21/2020
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Evrysdi (risdiplam)
Spinal Muscular Atrophy Indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

2 . Criteria

Product Name:Evrysdi	
Diagnosis	Spinal Muscular Atrophy
Approval Length	12 Months

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EVRYSDI	RISDIPLAM FOR SOLN 0.75 MG/ML	74706560002120	Brand

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA) Type I, II, or III [1-3, A]

AND

2 - Both of the following: [1-7]

2.1 The mutation or deletion of genes in chromosome 5q resulting in one of the following: [B]

2.1.1 Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

2.1.2 Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2.2 Patient has at least 2 copies of SMN2 [C]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy [2-3, D]

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [3, D]

AND

5 - At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability*: [2-7, E]

- Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Revised Upper Limb Module (RULM) Test (Non ambulatory)
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Motor Function Measure 32 (MFM-32) Scale
- Item 22 of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III)

AND

6 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

AND

7 - Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza) [2-3, 10, F]

AND

8 - One of the following: [2-3, 10, F]

8.1 Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma)

OR

8.2 Both of the following:

- Patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma)
- Documentation of inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)

Notes	*Baseline assessments for patients less than 2 months of age request ing risdiplam are not necessary in order to not delay access to initial t herapy in recently diagnosed infants. Initial assessments shortly post-t herapy can serve as baseline with respect to efficacy reauthorization assessment.

Product Name:Evrysdi	
Diagnosis	Spinal Muscular Atrophy
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EVRYSDI	RISDIPLAM FOR SOLN 0.75 MG/ML	74706560002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy from pretreatment baseline status as demonstrated by the most recent results from one of the following exams:

1.1 One of the following HINE-2 milestones: [2]

- Improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick
- Improvement or maintenance of previous improvement of at least a 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp
- Patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.2 One of the following HFMSE milestones: [8]

- Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.3 One of the following RULM test milestones: [2, 8-9]

- Improvement or maintenance of a previous improvement of at least a 2 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.4 One of the following CHOP INTEND milestones: [2]

- Improvement or maintenance of a previous improvement of at least a 4 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.5 One of the following MFM-32 milestones: [2]

- Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.6 Improvement in the ability to sit without support for at least 5 seconds as assessed by item 22 of the Gross Motor Scale of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III) [2-3]

AND

2 - Patient continues to not be dependent on invasive ventilation or tracheostomy [2-3, D]

AND

3 - Patient continues to not be dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [3, D]

AND

4 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

AND

5 - Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza) [2-3, 10, F]

AND

6 - One of the following: [2-3, 10, F]

6.1 Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma)

OR

6.2 Both of the following:

- Patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma)
- Documentation of inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)

3 . Endnotes

A. There were two major Phase 2/3 trials that the FDA assessed when determining Evrysdi's clinical efficacy and subsequent approval (SUNFISH and FIREFISH). SUNFISH only enrolled patients with SMA Types 2 and 3 and FIREFISH only enrolled patients with SMA Type 1. [2-3]
B. This is the definition that the clinical trials SUNFISH and FIREFISH used. Also consistent with clinical guidelines. [2-7]
C. FIREFISH required patients to have 2 copies of SMN2, and SUNFISH only enrolled patients with 2-4 copies of SMN2. [2-3]
D. Invasive ventilation or tracheostomy was an exclusion criteria in both the SUNFISH and FIREFISH trials. Use of non-invasive ventilation beyond use for naps and nighttime sleep was only an exclusion criteria in FIREFISH. [2-3]
E. MFM-32 was included in Evrysdi criteria but not Spinraza because Spinraza did not study MFM-32 as an endpoint. Baseline motor score standards was only used as an inclusion criterion for SUNFISH. Revised upper limb module (RULM) entry item A (Brooke score) equal to or greater than 2 AND MFM-32 (Item 9) scores equal to or greater than 1 were required. As this was only for the SUNFISH trial and only applied to some of the motor scores, it was deemed unnecessary to include as a criterion. [2]
F. A recent European ad-hoc consensus statement on SMA stated that there currently is no published evidence that the combination of two disease modifying therapies (e.g., Evrysdi and Zolgensma) is superior to any single treatment alone. Both FIREFISH and SUNFISH excluded patients that were on concomitant or previous treatment with either SMN2-targeting antisense oligonucleotide, or gene therapy (e.g., Spinraza or Zolgensma). JEWELFISH is an ongoing open label phase 2 trial that included patients previously treated with another SMA targeted therapy (e.g., Zolgensma, Spinraza). JEWELFISH is scheduled to be completed in January 2025. [2-3,10-11]

4 . References

1. Evrysdi prescribing information. Genentech, Inc. South San Francisco, CA. September 2024.
2. Day JW, Annoussamy M, Baranello G, et al. SUNFISH Part 2: 24-month efficacy outcomes of risdiplam (RG7916) treatment in patients with Type 2 or 3 spinal muscular atrophy (SMA). Presented at the 2020 Virtual SMA Research & Clinical Care Meeting. June 12, 2020.

3. Servais L, Baranello G, Masson R, et al. FIREFISH Part 2: Efficacy and safety of risdiplam (RG7916) in infants with Type 1 spinal muscular atrophy (SMA). Presented at the 2020 Virtual SMA Research & Clinical Care Meeting. June 12, 2020.
4. Markowitz JA, Sing P, Darras BT. Spinal muscular atrophy: a clinical and research update. Pediatr Neurol. 2012;46(1):1-12.
5. Wang CH, Finkel RS, Bertini ES, et al. Consensus statement for standard of care in spinal muscular atrophy. J Child Neurol. 2007;22(8):1027-1049.
6. Bertini E DJ, Muhaizea A, et al. RAINBOWFISH: A Study of Risdiplam (RG7916) in Newborns with Presymptomatic Spinal Muscular Atrophy. Presented at: World Muscle Society; October 1–5, 2019; Copenhagen, Denmark.
7. Mercuri E, Finkel RS, Muntoni F, et al. Diagnosis and management of spinal muscular atrophy: Part 1: Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. J Neuromuscul Dis. 2018;28(2):103-115.
8. Stolte B, Bois JM, Kizina K, et al. Minimal clinically important differences in functional motor scores in adults with spinal muscular atrophy. Eur. J. Neurol. 2020; 0:1-9.
9. Pera, M., Coratti, G., Mazzone, E., et al. (2019). Revised upper limb module for spinal muscular atrophy: 12 month changes. Muscle Nerve. Apr;59(4):426-430.
10. Kirschner J, Butoianu N, Goemans N, et al. European ad-hoc consensus statement on gene replacement therapy for spinal muscular atrophy. Eur J Paediatr Neurol. 2020. https://doi.org/10.1016/j.ejpn.2020.07.001
11. Evrysdi [AMCP dossier]; South San Francisco, CA: Genentech; September 2020.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228856
Guideline Name	Extended Release Tramadol Products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Conzip
Pain Indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate. Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve CONZIP for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. CONZIP is not indicated as an as-needed (prn) analgesic.
Drug Name: Tramadol Extended Release (ER)
Pain Indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate. Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosages or duration, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve tramadol hydrochloride extended-release tablets for use in patients for whom alternative treatment

options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Tramadol hydrochloride extended-release tablet is not indicated as an as-needed (prn) analgesic.

2 . Criteria

Product Name:ConZip, tramadol ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRAMADOL HCL ER	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 100 MG	65100095107070	Generic
CONZIP	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 100 MG	65100095107070	Generic
TRAMADOL HCL ER	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 200 MG	65100095107080	Generic
CONZIP	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 200 MG	65100095107080	Generic
TRAMADOL HCL ER	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 300 MG	65100095107090	Generic
CONZIP	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 300 MG	65100095107090	Generic
TRAMADOL HCL ER	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 150 MG	65100095107075	Generic
TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR 100 MG	65100095107520	Generic
TRAMADOL HYDROCHLORIDE ER	TRAMADOL HCL TAB ER 24HR 100 MG	65100095107520	Generic
TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR 200 MG	65100095107530	Generic
TRAMADOL HYDROCHLORIDE ER	TRAMADOL HCL TAB ER 24HR 200 MG	65100095107530	Generic
TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR 300 MG	65100095107540	Generic
TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR BIPHASIC RELEASE 100 MG	65100095107560	Generic

TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR BIPHASIC RELEASE 200 MG	65100095107570	Generic
TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR BIPHASIC RELEASE 300 MG	65100095107580	Generic

Approval Criteria

1 - Diagnosis of moderate to moderately severe chronic pain

AND

2 - Trial and failure (of a minimum 30 day supply) or intolerance to an immediate release tramadol containing product (e.g., tramadol, tramadol/acetaminophen)

3 . References

1. Conzip prescribing information. Vectical Pharmaceuticals, LLC. Bridgewater, NJ. December 2023.
2. Tramadol Extended Release prescribing information. Lupin Pharmaceuticals, Inc. Baltimore, MD. January 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228649
Guideline Name	Eysuvis (loteprednol etabonate ophthalmic suspension)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Eysuvis (loteprednol etabonate ophthalmic suspension)
Dry eye disease (DED) Indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

2 . Criteria

Product Name:Eysuvis	
Diagnosis	Dry Eye Disease
Approval Length	14 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EYSUVIS	LOTEPREDNOL ETABONATE OPHTH SUSP 0.25%	86300035101825	Brand

Approval Criteria

1 - Diagnosis of dry eye disease

AND

2 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

Product Name:Eysuvis	
Diagnosis	Dry Eye Disease
Approval Length	14 Day(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EYSUVIS	LOTEPREDNOL ETABONATE OPHTH SUSP 0.25%	86300035101825	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in dry eye symptoms)

AND

2 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

3 . References

1. Eysuvis prescribing information. Kala Pharmaceuticals, Inc. Watertown, MA. November 2020.
2. Per clinical consult with ophthalmologist, December 21, 2020.
3. Shtein, RM. Dry eye disease. In: Post T, ed. UpToDate. UpToDate; 2020. Accessed December 16, 2020. www.uptodate.com
4. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): IBM Corporation.; Updated periodically. Available by subscription at: https://www.micromedexsolutions.com/. Accessed December 16, 2020.

Prior Authorization Guideline

Guideline ID	GL-228419
Guideline Name	Fabhalta (iptacopan)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Fabhalta (iptacopan)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH). **Immunoglobulin A nephropathy (IgAN)** Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g. This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether Fabhalta slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

2 . Criteria

Product Name:Fabhalta	
Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FABHALTA	IPTACOPAN HCL CAP 200 MG	85807535200130	Brand

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Hemoglobin level of less than 10 g/dL

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Fabhalta	
Diagnosis	paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FABHALTA	IPTACOPAN HCL CAP 200 MG	85807535200130	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions)

Product Name:Fabhalta	
Diagnosis	Immunoglobulin A nephropathy (IgAN)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FABHALTA	IPTACOPAN HCL CAP 200 MG	85807535200130	Brand

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy [A]

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool] [B]

AND

3 - Used to reduce proteinuria

AND

4 - Patient has an estimated glomerular filtration rate (eGFR) of greater than or equal to 20 mL/min/1.73 m2

AND

5 - Patient has been on a minimum 90-day trial of a maximally tolerated dose of one of the following:

- An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

AND

6 - Prescribed by or in consultation with a nephrologist

Product Name:Fabhalta	
Diagnosis	Immunoglobulin A nephropathy (IgAN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FABHALTA	IPTACOPAN HCL CAP 200 MG	85807535200130	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as demonstrated by a decrease in urine protein-to-creatinine ratio (UPCR) from baseline

3 . Endnotes

A. IgAN can only be diagnosed with a kidney biopsy [2]
B. The International IgAN Prediction Tool incorporates clinical information at the time of biopsy and is a valuable resource to quantify risk of progression and inform shared decision-making with patients [2]

4 . References

1. Fabhalta Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. August 2024.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021;100(4S):S1-S276.

Prior Authorization Guideline

Guideline ID	GL-233201
Guideline Name	Fabry Disease Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/20/2004
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Fabrazyme (agalsidase beta)
Fabry disease Indicated for the treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease.
Drug Name: Elfabrio (pegunigalsidase alfa-iwxj)
Fabry disease Indicated for the treatment of adults with confirmed Fabry disease.

2 . Criteria

Product Name:Fabrazyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FABRAZYME	AGALSIDASE BETA FOR IV SOLN 5 MG	30903610102110	Brand
FABRAZYME	AGALSIDASE BETA FOR IV SOLN 35 MG	30903610102120	Brand

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Patient is 2 years of age or older

AND

3 - One of the following: [3, 4]

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing
- Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

4 - Will not be used in combination with other drugs used for Fabry disease [A]

Product Name:Fabrazyme	
Approval Length	24 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FABRAZYME	AGALSIDASE BETA FOR IV SOLN 5 MG	30903610102110	Brand
FABRAZYME	AGALSIDASE BETA FOR IV SOLN 35 MG	30903610102120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Elfabrio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ELFABRIO	PEGUNIGALSIDASE ALFA-IWXJ IV SOLUTION 20 MG/10 ML	30903660102020	Brand
ELFABRIO	PEGUNIGALSIDASE ALFA-IWXJ IV SOLUTION 5 MG/2.5 ML	30903660102005	Brand

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Disease confirmed by one of the following: [3, 4]

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing
- Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

3 - Will not be used in combination with other drugs used for Fabry Disease [A]

Product Name:Elfabrio	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ELFABRIO	PEGUNIGALSIDASE ALFA-IWXJ IV SOLUTION 20 MG/10 ML	30903660102020	Brand
ELFABRIO	PEGUNIGALSIDASE ALFA-IWXJ IV SOLUTION 5 MG/2.5 ML	30903660102005	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. The safety and effectiveness of concomitant use of Galafold (migalastat) and Fabrazyme (agalsidase beta) has not been established. [2, 6]

4 . References

1. Fabrazyme prescribing information. Genzyme Corporation. Cambridge, MA. July 2024.
2. Per clinical consultation with geneticist. October 11, 2018.
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5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-233266
Guideline Name	Fasenra (benralizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	1/24/2018
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Fasenra (benralizumab)
Severe Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. Limitations of use: Fasenra is not indicated for treatment of other eosinophilic conditions. Fasenra is not indicated for the relief of acute bronchospasm or status asthmaticus. **Eosinophilic Granulomatosis with Polyangiitis:** Indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

2 . Criteria

Product Name:Fasenra	
Diagnosis	Severe Asthma
Approval Length	6 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FASENRA	BENRALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 30 MG/ML	4460402000E520	Brand
FASENRA PEN	BENRALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 30 MG/ML	4460402000D520	Brand
FASENRA	BENRALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 10 MG/0.5ML	4460402000E515	Brand

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [5, B, F]

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [2, 3, B]

OR

3.2 Prior asthma-related hospitalization within the past 12 months [C]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Patient is 6 years of age or older but less than 12 years of age

AND

4.1.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1.2.1 Both of the following [A, 4, 5]:

- Medium-dose inhaled corticosteroid (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.1.2.2 One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg])

OR

4.2 Both of the following:

4.2.1 Patient is 12 years of age or older

AND

4.2.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.2.2.1 Both of the following [4, 5, A]:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)

- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.2.2.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg])

AND

5 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name:Fasenra	
Diagnosis	Severe Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FASENRA	BENRALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 30 MG/ML	4460402000E520	Brand
FASENRA PEN	BENRALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 30 MG/ML	4460402000D520	Brand
FASENRA	BENRALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 10 MG/0.5ML	4460402000E515	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name:Fasenra	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FASENRA	BENRALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 30 MG/ML	4460402000E520	Brand
FASENRA PEN	BENRALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 30 MG/ML	4460402000D520	Brand
FASENRA	BENRALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 10 MG/0.5ML	4460402000E515	Brand

Approval Criteria

1 - Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)

AND

2 - Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy)

AND

3 - Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone) unless there is a contraindication or intolerance to corticosteroid therapy

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Rheumatologist
- Allergist/Immunologist

Product Name:Fasenra	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FASENRA	BENRALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 30 MG/ML	4460402000E520	Brand
FASENRA PEN	BENRALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 30 MG/ML	4460402000D520	Brand
FASENRA	BENRALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 10 MG/0.5ML	4460402000E515	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increase in remission time)

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [4]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400
DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.			

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [4]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Beclometasone dipropionate (pMDI, extrafine particle, HFA)	50-100	> 100-200	> 200
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Budesonide (nebules)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle*, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50		n.a.
Fluticasone propionate (DPI)	50-100	> 100-200	> 200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	> 100-200	> 200
Mometasone furoate (pMDI, standard particle, HFA)	100		200

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [5]
B. The SIROCCO and CALIMA trials evaluated the effect of benralizumab 30mg administered in 4 week and 8 week regimens as add on therapy to standard of care medicine. The trials enrolled patients 12 to 75 years of age with severe asthma defined as a history of two or more exacerbations in the previous year which needed systemic corticosteroids or a temporary increase in the patient's usual maintenance dose of oral corticosteroids. Patients were also required to have received treatment with a medium dose or high dose ICS plus LABA for at least one year before enrollment. Both trials confirmed benralizumab significantly reduced the annual exacerbation rates and was generally well tolerated in patients who were uncontrolled on high dose ICS plus LABA and had a baseline blood eosinophil count of 300 cells per microliter or greater [2, 3]. The baseline eosinophil level requirement of greater than or equal to 150 cells per microliter and the requirement for a history of one or more exacerbations listed in the criteria comes from the inclusion criteria allowed in the ZONDA trial. The ZONDA trial was a 28-week, Phase 3, randomized, double blind, placebo controlled, multicenter, oral corticosteroid reduction trial [6].
C. Recommendation inferred from the national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.
D. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However, the

approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence, and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [5].

E. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [5]
F. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [7]

5 . References

1. Fasenra Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. April 2024.
2. FitzGerald JM, Bleecker ER, Nair P, et al. Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet. 2016 Oct 29;388(10056):2128-2141.
3. Bleecker ER, FitzGerald JM, Chanez P, et al. Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting Beta two agonist (SIROCCO): a randomised, multicentre, placebo-controlled phase 3 trial. Lancet. 2016 Oct 29;388(10056):2115-2127.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2023 update). 2023 www.ginasthma.org. Accessed April 2024.
5. Nair P, Wenzel S, Rabe KF, et al. ZONDA Trial Investigators. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. N Engl J Med. 2017;376(25):2448-2458.
6. Institute for Clinical and Economic Review (ICER). Biologic therapies for treatment of asthma associated with type 2 inflammation: effectiveness, value, and value-based price benchmarks. https://icer.org/wp-content/uploads/2020/10/ICER_Asthma-Final-Report_Unredacted_08122020.pdf. Published December 20, 2018. Accessed April 15, 2022.
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6 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228858
Guideline Name	Fecal Microbiota Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rebyota (fecal microbiota, live-jslm) suspension
Recurrent Clostridioides difficile infection (CDI) Indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI. Limitations of use: Rebyota is not indicated for treatment of CDI.
Drug Name: Vowst (fecal microbiota spores, live-brpk) capsule
Recurrent Clostridioides difficile infection (CDI) Indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI). Limitations of use: Vowst is not indicated for treatment of CDI.
Drug Name: Zinplava (bezlotoxumab) injection
Recurrent Clostridioides difficile infection (CDI) Indicated to reduce recurrence of Clostridioides difficile infection (CDI) in adults and pediatric patients 1 year of age and older

who are receiving antibacterial drug treatment for CDI and are at high risk for CDI recurrence.
Limitations of use: Zinplava is not indicated for the treatment of CDI.

2 . Criteria

Product Name:Rebyota	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REBYOTA	FECAL MICROBIOTA, LIVE-JSLM RECTAL SUSP 150 ML	52522010301820	Brand

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of one or more recurrent episodes of CDI

AND

4 - Both of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

Product Name:Rebyota	
Approval Length	14 Day(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
REBYOTA	FECAL MICROBIOTA, LIVE-JSLM RECTAL SUSP 150 ML	52522010301820	Brand

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of one or more recurrent episodes of CDI

AND

4 - Both of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

Product Name:Vowst	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOWST	FECAL MICROBIOTA SPORES, LIVE-BRPK CAPS	52522020100120	Brand

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of two or more recurrent episodes of CDI within 12 months

AND

4 - All of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst [A]

AND

4.3 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

AND

6 - Trial and failure, contraindication or intolerance to Rebyota

Product Name:Vowst	
Approval Length	14 Day(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VOWST	FECAL MICROBIOTA SPORES, LIVE-BRPK CAPS	52522020100120	Brand

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of two or more recurrent episodes of CDI within 12 months

AND

4 - All of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst [A]

AND

4.3 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to Rebyota

Product Name:Zinplava	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZINPLAVA	BEZLOTOXUMAB IV SOLN 1000 MG/40ML (25 MG/ML)	19503015002020	Brand

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements in less than or equal to 24 hours
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Used for the reduction of the recurrence of CDI

AND

3 - Used in combination with antibacterial drug treatment for CDI [e.g., oral Vancocin (vancomycin), Flagyl (metronidazole), or Dificid (fidaxomicin)]

AND

4 - Patient is 1 year of age or older

AND

5 - Patient has one or more of the following risk factors associated with CDI recurrence: [5-8, B]

- One or more prior episodes of CDI in the previous 6 months
- Immunocompromised
- Chronic dialysis
- Inflammatory bowel disease
- Continued use of non-CDI antimicrobials after diagnosis of CDI and/or after CDI treatment

AND

6 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

3 . Endnotes

A. Patients are required to take magnesium citrate 24 hours prior to the first dose of Vowst per the prescribing information. There is currently no efficacy data regarding the use of Vowst without magnesium citrate and the thought is that it helps to clear the antibiotics prior to administration of Vowst. [2,3]

B. Risk factors for CDI recurrence: There is no specific guidance in regards to which patients should be considered high risk for CDI recurrence. There are a multitude of risk factors that increase patients' risk for recurrent CDI. Risk factors reported in one or more previously published studies and confirmed by consultant feedback include: one or more prior episodes of CDI in the previous 6 months, immunocompromised state, renal failure, inflammatory bowel disease, and continued use of non-CDI antimicrobials. Although patients greater than or equal to 65 years of age are at greater risk of recurrent CDI than younger patients, per consultant feedback, not all patients over 65 should be treated with Zinplava, only those with the highest risk. [5-11]

4 . References

1. Rebyota Prescribing Information. Ferring Pharmaceuticals, Inc. Parsippany, NJ. November 2022.
2. Vowst Prescribing Information. Aimmune Therapeutics, Inc. Brisbane, CA. April 2023.
3. Per clinical consult with gastroenterologist, May 3, 2023.
4. Zinplava Prescribing Information. Merck Sharp & Dohme LLC. Rahway, NJ. May 2023.

5. Cohen SH, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). Infect Control Hosp Epidemiol. 2010;31(5):431-55.
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7. Zinplava Product Dossier. Merck and Co., Inc. November 2016.
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11. Per clinical consult with gastroenterologist, December 28, 2016.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Femring (estradiol acetate ring)

Prior Authorization Guideline

Guideline ID	GL-228421
Guideline Name	Femring (estradiol acetate ring)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Femring (estradiol acetate vaginal ring)
Moderate to Severe Vasomotor Symptoms Indicated for the treatment of moderate to severe vasomotor symptoms due to menopause. **Moderate to Severe Vulvar and Vaginal Atrophy** Indicated for the treatment of moderate to severe vulvar and vaginal atrophy due to menopause.

2 . Criteria

Product Name:Femring	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
FEMRING	ESTRADIOL ACETATE VAGINAL RING 0.05 MG/24HR	55350020109020	Brand
FEMRING	ESTRADIOL ACETATE VAGINAL RING 0.1 MG/24HR	55350020109030	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of vulvar and vaginal atrophy due to menopause

AND

1.2 Trial and failure (of a minimum 28-day supply), contraindication or intolerance to one of the following:

- Premarin vaginal cream
- Imvexxy
- Osphena

OR

2 - Used for moderate to severe vasomotor symptoms due to menopause

3 . References

1. Femring Prescribing Information. Millicent U.S., Inc. East Hanover, NJ. November 2013.

Ferriprox (deferiprone)

Prior Authorization Guideline

Guideline ID	GL-228860
Guideline Name	Ferriprox (deferiprone)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ferriprox (deferiprone) Tablets
Iron Overload Indicated for the treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with thalassemia syndromes, sickle cell disease or other anemias. Limitations of Use: Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

Drug Name: Ferriprox (deferiprone) Oral Solution
Iron Overload Indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with thalassemia syndromes, sickle cell disease or other anemias. Limitations of Use: Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

2 . Criteria

Product Name:Ferriprox oral solution, Generic deferiprone tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FERRIPROX	DEFERIPRONE ORAL SOLN 100 MG/ML	93100028002020	Brand
DEFERIPRONE	DEFERIPRONE TAB 500 MG	93100028000320	Generic
DEFERIPRONE	DEFERIPRONE TAB 1000 MG	93100028000340	Generic

Approval Criteria

1 - Diagnosis of transfusional iron overload due to one of the following: [1]

- Thalassemia syndromes
- Sickle cell disease
- Other transfusion-dependent anemias

AND

2 - One of the following:

2.1 For Ferriprox oral solution, patient is 3 years of age or older

OR

2.2 For generic deferiprone tablet, patient is 8 years of age or older

AND

3 - Trial (of a minimum 30 day supply) and failure (defined by a serum ferritin > 2,500 mcg/L), contraindication or intolerance to one of the following chelation therapy [A]:

- Generic deferoxamine
- Generic deferasirox

AND

4 - Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L

Product Name:Brand Ferriprox tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FERRIPROX	DEFERIPRONE TAB 500 MG	93100028000320	Brand
FERRIPROX	DEFERIPRONE ORAL SOLN 100 MG/ML	93100028002020	Brand
FERRIPROX	DEFERIPRONE TAB 1000 MG	93100028000340	Brand
FERRIPROX TWICE-A-DAY	DEFERIPRONE (TWICE DAILY) TAB 1000 MG	93100028000345	Brand
DEFERIPRONE	DEFERIPRONE TAB 500 MG	93100028000320	Generic
DEFERIPRONE	DEFERIPRONE TAB 1000 MG	93100028000340	Generic

Approval Criteria

1 - Diagnosis of transfusional iron overload due to one of the following: [1]

- Thalassemia syndromes
- Sickle cell disease
- Other transfusion-dependent anemias

AND

2 - Patient is 8 years of age or older

AND

3 - Trial (of a minimum 30 day supply) and failure (defined by a serum ferritin > 2,500 mcg/L), contraindication or intolerance to one of the following chelation therapy [A]:

- Generic deferoxamine
- Generic deferasirox

AND

4 - Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L

AND

5 - Trial and failure, or intolerance to generic deferiprone tablets*

Notes	*Product may require prior authorization

Product Name:Brand Ferriprox tablet, Ferriprox oral solution, Generic deferiprone tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FERRIPROX	DEFERIPRONE TAB 500 MG	93100028000320	Brand
FERRIPROX	DEFERIPRONE ORAL SOLN 100 MG/ML	93100028002020	Brand
FERRIPROX	DEFERIPRONE TAB 1000 MG	93100028000340	Brand
FERRIPROX TWICE-A-DAY	DEFERIPRONE (TWICE DAILY) TAB 1000 MG	93100028000345	Brand
DEFERIPRONE	DEFERIPRONE TAB 500 MG	93100028000320	Generic
DEFERIPRONE	DEFERIPRONE TAB 1000 MG	93100028000340	Generic

Approval Criteria

1 - Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline

AND

2 - Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L

AND

3 - For Brand Ferriprox tablets, trial and failure, or intolerance to generic deferiprone tablets

3 . Endnotes

A. Failure to prior chelation therapy is defined as serum ferritin > 2,500 mcg/L. [1]

4 . References

1. Ferriprox tablets prescribing information. Apotex Inc., Toronto, Canada. July 2023.
2. Ferriprox solution prescribing information. Apotex Inc., Toronto, Canada. November 2021.
3. Deferiprone prescribing information. Taro Pharmaceutical Industries Ltd. Haifa Bay, Israel. January 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228424
Guideline Name	Fibric Acid Derivatives
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Fenoglide, Fibricor
Primary Hypercholesterolemia and Mixed Dyslipidemia Indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), triglycerides (TG), and apolipoprotein B (Apo B), and to increase high-density lipoprotein (HDL-C) in adult patients with primary hypercholesterolemia or mixed dyslipidemia. Limitations of Use: Fenofibrate was not shown to reduce coronary heart disease morbidity and mortality in patients with type 2 diabetes mellitus. **Severe Hypertriglyceridemia** Indicated as adjunctive therapy to diet for treatment of adult patients with severe hypertriglyceridemia. Improving glycemic control in diabetic patients showing fasting chylomicronemia will usually reduce fasting triglycerides and eliminate chylomicronemia thereby obviating the need for pharmacologic intervention. Markedly elevated levels of serum triglycerides (e.g., > 2000 mg/dL) may increase the risk of developing pancreatitis. The effect of fenofibrate therapy on reducing this risk has not been adequately studied. Limitations of Use: Fenofibrate was not shown to reduce coronary heart disease morbidity and mortality in patients with type 2 diabetes mellitus.

2 . Criteria

Product Name:Brand Fenoglide, Brand Fibricor	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
FENOGLIDE	FENOFIBRATE TAB 40 MG	39200025000308	Brand
FENOGLIDE	FENOFIBRATE TAB 120 MG	39200025000322	Brand
FIBRICOR	FENOFIBRIC ACID TAB 35 MG	39200024000320	Brand
FIBRICOR	FENOFIBRIC ACID TAB 105 MG	39200024000340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure or intolerance to a minimum 30 day supply to both of the following:

2.1 One of the following generics:

- fenofibrate micronized capsule
- fenofibrate tablet
- fenofibric capsule
- fenofibric acid tablet

AND

2.2 One of the following:

- Brand Lipofen
- Generic fenofibrate capsule

3 . References

1. Fenoglide Prescribing Information. Salix Pharmaceuticals. Bridgewater, NJ. June 2021.
2. Fibricor Prescribing Information. Athena Bioscience, LLC. Athena, GA. December 2020.

Prior Authorization Guideline

Guideline ID	GL-233280
Guideline Name	Filspari (sparsentan)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	4/19/2023
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Filspari (sparsentan)
Primary immunoglobulin A nephropathy (IgAN) Indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

2 . Criteria

Product Name:Filspari	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FILSPARI	SPARSENTAN TAB 200 MG	56483065000320	Brand
FILSPARI	SPARSENTAN TAB 400 MG	56483065000340	Brand

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy [A]

AND

2 - Patient is at risk of rapid disease progression [e.g., proteinuria greater than 0.75 - 1 g/day, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool] [B,C]

AND

3 - Used to slow kidney function decline

AND

4 - Patient has an estimated glomerular filtration rate (eGFR) of greater than or equal to 30 mL/min/1.73 m2

AND

5 - Patient has been on a minimum 90-day trial of a maximally tolerated dose of one of the following:

- An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

AND

6 - Medication will not be used in combination with any of the following:

- Angiotensin receptor blockers or angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril/valsartan)]
- Endothelin receptor antagonists (ERAs) [e.g., Letairis (ambrisentan), Tracleer (bosentan), Opsumit (macitentan)]
- Tekturna (aliskiren)

AND

7 - Prescribed by or in consultation with a nephrologist

Product Name:Filspari	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FILSPARI	SPARSENTAN TAB 200 MG	56483065000320	Brand
FILSPARI	SPARSENTAN TAB 400 MG	56483065000340	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as demonstrated by a decrease in urine protein-to-creatinine ratio (UPCR) from baseline

AND

2 - Medication is not taken in combination with any of the following:

- Angiotensin receptor blockers or angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril/valsartan)]
- Endothelin receptor antagonists (ERAs) [e.g., Letairis (ambrisentan), Tracleer (bosentan), Opsumit (macitentan)]

- Tekturna (aliskiren)

3 . Endnotes

A. IgAN can only be diagnosed with a kidney biopsy. [2]
B. The International IgAN Prediction Tool incorporates clinical information at the time of biopsy and is a valuable resource to quantify risk of progression and inform shared decision-making with patients. [2]
C. High risk of progression in IgAN is currently defined as proteinuria >0.75–1 g/d despite ‡90 days of optimized supportive care [2]

4 . References

1. Filspari Package Insert. Travere Therapeutics, Inc. San Diego, CA. August 2024.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021;100(4S):S1-S276.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228651
Guideline Name	Filsuvez (birch triterpenes) - PA, NF, QL
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: FILSUVEZ (birch triterpenes) topical gel
Wounds Associated with Dystrophic and Junctional Epidermolysis Bullosa Indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older.

2 . Criteria

Product Name:Filsuvez	
Approval Length	3 months [A,1]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FILSUVEZ	BIRCH TRITERPENES GEL 10%	90944020004030	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Dystrophic epidermolysis bullosa (DEB)
- Junctional epidermolysis bullosa (JEB)

AND

2 - Disease is confirmed by one of the following: [4-6, 10]

2.1 Genetic testing confirms mutation in one of the following genes:

2.1.1 For Dystrophic epidermolysis bullosa (DEB), collagen type VII (COL7A1)

OR

2.1.2 For Junctional epidermolysis bullosa (JEB), one of the following:

- ITGA6
- ITGB4
- collagen type XVII (COL17A1)
- LAMA3
- LAMB3
- LAMC2
- ITGA3
- LAMA3A

OR

2.2 Skin biopsy

AND

3 - Patient is 6 months of age or older

AND

4 - Medication is being used for the treatment of wounds that require healing

AND

5 - Target wound(s) meets all of the following: [B, 1, 7]

- Present for at least 21 days
- No signs of infection
- No evidence or history of basal or squamous cell carcinoma

AND

6 - Patient does not have history of stem cell transplant [7]

AND

7 - Medication is not being used concurrently with other FDA approved therapies (e.g.,Vyjuvek) on the same target wound for the treatment of epidermolysis bullosa

AND

8 - Standard wound care management not adequate in healing wounds (e.g., daily wound dressings, pain management, controlling infections)

AND

9 - Prescribed by or in consultation with a specialist with expertise in wound care

Product Name:Filsuvez	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FILSUVEZ	BIRCH TRITERPENES GEL 10%	90944020004030	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by wound healing (e.g., reduction in number or size of wounds) [C, 1]

AND

2 - Wound(s) being treated continues to meet both of the following:

- No signs of infection
- No evidence or history of basal or squamous cell carcinoma

AND

3 - Medication is not being used concurrently with other FDA approved therapies (e.g.,Vyjuvek) on the same target wound for the treatment of epidermolysis bullosa

AND

4 - Prescribed by or in consultation with a specialist with expertise in wound care

Product Name:Filsuvez	
Approval Length	3 months [A,1]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
FILSUVEZ	BIRCH TRITERPENES GEL 10%	90944020004030	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Dystrophic epidermolysis bullosa (DEB)
- Junctional epidermolysis bullosa (JEB)

AND

2 - Submission of medical records (e.g., chart notes) documenting that disease is confirmed by one of the following: [4-6, 10]

2.1 Genetic testing confirms mutation in one of the following genes:

2.1.1 For Dystrophic epidermolysis bullosa (DEB), collagen type VII (COL7A1)

OR

2.1.2 For Junctional epidermolysis bullosa (JEB), one of the following:

- ITGA6
- ITGB4
- collagen type XVII (COL17A1)
- LAMA3
- LAMB3
- LAMC2
- ITGA3
- LAMA3A

OR

2.2 Skin biopsy

AND

3 - Patient is 6 months of age or older

AND

4 - Medication is being used for the treatment of wounds that require healing

AND

5 - Target wound(s) meets all of the following: [B, 1, 7]

- Present for at least 21 days
- No signs of infection
- No evidence or history of basal or squamous cell carcinoma

AND

6 - Patient does not have history of stem cell transplant [7]

AND

7 - Medication is not being used concurrently with other FDA approved therapies (e.g.,Vyjuvek) on the same target wound for the treatment of epidermolysis bullosa

AND

8 - Submission of medical records (e.g., chart notes) confirming that standard wound care management not adequate in healing wounds (e.g., daily wound dressings, pain management, controlling infections)

AND

9 - Prescribed by or in consultation with a specialist with expertise in wound care

Product Name:Filsuvez	
Approval Length	12 month(s)

Guideline Type	Quantity Limit Override

Product Name	Generic Name	GPI	Brand/Generic
FILSUVEZ	BIRCH TRITERPENES GEL 10%	90944020004030	Brand

Approval Criteria

1 - Quantity limit restriction has been deemed insufficient in the treatment of the member's disease or medical condition

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following: [D]

- Patient total body surface area (m^2) to be treated
- Frequency of wound dressing changes

AND

3 - Requested quantity does not exceed one tube per 0.025m^2 surface area being treated*

AND

4 - Prescribed by or in consultation with a specialist with expertise in wound care

Notes	*Clinician to confirm requested quantity is appropriate based on total BSA provided and frequency of administration (one tube covers up to 0.025m^2 surface area. A tube of Filsuvez is for one-time use and should be discarded once opened)

3 . Definitions

Definition	Description

Epidermolysis Bullosa (EB)	EB is a rare, inherited connective tissue disorder that causes abnormalities in the cohesion of the layers of the epidermis that can lead to fragile skin, resulting in blisters, erosions, nonhealing ulceration, and scars in response to mild skin trauma. EB is classified into four major types based upon the level at which blisters develop in the epidermis and basement membrane zone: Epidermolysis bullosa simplex (EBS), Junctional epidermolysis bullosa (JEB), Dystrophic epidermolysis bullosa (DEB), and Kindler epidermolysis bullosa (KEB or Kindler syndrome). The specific type of EB is determined by the affected gene.Three types are further classified into more than 30 total subtypes based on clinical, pathophysiologic, and molecular criteria. Some subtypes of EB are associated with cutaneous malignancy.There is no cure for EB. The current standard of care for EB is supportive, which includes daily wound care, pain management, and protective bandaging. [2-3]

4 . Endnotes

A. Subjects received topical treatment with either Filsuvez or a placebo gel on partial-thickness wounds every 1 to 4 days for a total of 90 days. Treated wounds were covered with non-adhesive dressings. Following completion of the double-blind phase, all subjects received FILSUVEZ for a total of 24 months during the open-label phase. [1]
B. If a Filsuvez- treated wound becomes infected, discontinue treatment to that wound until the infection has resolved. [1]
C. Apply Filsuvez to cleansed wounds with wound dressing changes until the wound is healed. [1]
D. One tube of FILSUVEZ covers up to 250 cm^2 surface area. A tube of Filsuvez is for one-time use and should be discarded once opened [1, 12]

5 . References

1. Filsuvez Prescribing Information. Lichtenheldt GmbH Pharmazeutische Fabrik. Wahlstedt Germany. December 2023.
2. Optum IPD Analytics. Available at: Dermatology: Epidermolysis Bullosa (ipdanalytics.com). Accessed March 25, 2024.
3. About EB. Available at: https://www.debra.org/about-eb. Accessed March 25, 2024.
4. Pfendner, E., and Lucky, A. Dystrophic Epidermolysis Bullosa. Available at: https://www.ncbi.nlm.nih.gov/books/NBK1304/#:~:text=Dystrophic%20epidermolysis%20bullosa%20(DEB)%20is,dystrophic%20epidermolysis%20bullosa%20(DDEB). Accessed March 25, 2024.

5. Peraza, D. Epidermolysis Bullosa. Available at: https://www.merckmanuals.com/professional/dermatologic-disorders/bullous-diseases/epidermolysis-bullosa. Accessed March 25, 2024.
6. What is EB. Available at: https://www.debra-international.org/what-is-eb#:~:text=EB%20is%20a%20group%20of,with%20more%20than%2030%20subtypes. Accessed March 25, 2024.
7. ClinicalTrials.gov. Phase III Efficacy and Safety Study of Oleogel-S10 in Epidermolysis Bullosa (EASE). Available at: https://www.clinicaltrials.gov/study/NCT03068780?cond=NCT03068780&rank=1#participation-criteria. Accessed March 25, 2024.
8. UptoDate. Diagnosis of epidermolysis bullosa. Available at: https://www.uptodate.com/contents/diagnosis-of-epidermolysis-bullosa. Accessed March 25, 2024.
9. UptoDate. Overview of the management of epidermolysis bullosa. Available at: https://www.uptodate.com/contents/overview-of-the-management-of-epidermolysis-bullosa?search=epidermolysis%20bullosa&source=search_result&selectedTitle=2%7E91&usage_type=default&display_rank=2. Accessed March 25, 2024.
10. UptoDate. Epidermolysis bullosa: Epidemiology, pathogenesis, classification, and clinical features. Available at: https://www.uptodate.com/contents/epidermolysis-bullosa-epidemiology-pathogenesis-classification-and-clinical-features?search=epidermolysis%20bullosa&source=search_result&selectedTitle=1%7E91&usage_type=default&display_rank=1. Accessed March 25, 2024.
11. Kern, J., Schwieger-Briel, A., Lowe, S., et al. Oleogel-S10 Phase 3 study “EASE” for epidermolysis bullosa: study design and rationale. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6560757/. Accessed March 26, 2024.
12. Filsuvez Prescription Form. Available at: https://resources.chiesiusa.com/Filsuvez/Filsuvez_Prescription_Form.pdf, Accessed July 24, 2024.

Prior Authorization Guideline

Guideline ID	GL-228426
Guideline Name	Fintepla (fenfluramine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Fintepla (fenfluramine)
Dravet Syndrome Indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. **Lennox-Gastaut Syndrome** Indicated for the treatment of seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older.

2 . Criteria

Product Name:Fintepla	
Diagnosis	Dravet Syndrome
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FINTEPLA	FENFLURAMINE HCL ORAL SOLN 2.2 MG/ML	72600028102020	Brand

Approval Criteria

1 - Diagnosis of seizures associated with Dravet syndrome

AND

2 - Patient is 2 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Trial and failure, contraindication or intolerance to one of the following:

- valproic acid
- clobazam

AND

3.1.2 Trial and failure, contraindication or intolerance to one of the following:

- Diacomit (stiripentol)
- Epidiolex (cannabidiol)
- topiramate
- zonisamide
- levetiracetam
- Briviact (brivaracetam)

OR

3.2 For continuation of prior therapy

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Fintepla	
Diagnosis	Lennox-Gastaut Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FINTEPLA	FENFLURAMINE HCL ORAL SOLN 2.2 MG/ML	72600028102020	Brand

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

2 - Patient is 2 years of age or older

AND

3 - ONE of the following:

- Trial and inadequate response, contraindication, or intolerance to TWO formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate) [2, A]
- For continuation of prior therapy

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Fintepla	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FINTEPLA	FENFLURAMINE HCL ORAL SOLN 2.2 MG/ML	72600028102020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by the reduction in seizure frequency from baseline

3 . Endnotes

A. The International League Against Epilepsy (ILAE) refers to drug-resistant epilepsy as the failure of adequate trials of two tolerated, appropriately chosen, and used ASM schedules, whether as monotherapy or in combination, to achieve sustained seizure freedom [2]

4 . References

1. Fintepla prescribing information. Zogenix Inc. Emeryville, CA. March 2022.
2. Fattorusso, A., Matricardi et al. The Pharmacoresistant Epilepsy: An Overview on Existing and New Emerging Therapies. Frontiers in Neurology. June 2021. Available at https://www.frontiersin.org/articles/10.3389/fneur.2021.674483/full. Accessed May 6, 2022.
3. LGS Foundation. Lennox-Gastaut Syndrome. Available at https://www.lgsfoundation.org/. Accessed May 8, 2022.

4. UptoDate. Lennox-Gastaut Syndrome. Available at https://www.uptodate.com/contents/epilepsy-syndromes-in-children?search=lennox%20gastaut%20syndrome&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#H9. Accessed May 8, 2022.

Prior Authorization Guideline

Guideline ID	GL-228857
Guideline Name	Flurazepam
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Flurazepam
Insomnia Indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakening. Since insomnia is often transient and intermittent, short-term use is usually sufficient. Prolonged use of hypnotics is usually not indicated and should only be undertaken concomitantly with appropriate evaluation of the patient.

2 . Criteria

Product Name:Flurazepam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FLURAZEPAM HCL	FLURAZEPAM HCL CAP 15 MG	60201010100105	Generic
FLURAZEPAM HCL	FLURAZEPAM HCL CAP 30 MG	60201010100110	Generic

Approval Criteria

1 - Diagnosis of insomnia

AND

2 - Trial and failure, contraindication, or intolerance to two of the following benzodiazepines: [A]

- Estazolam
- Halcion (triazolam)
- Restoril (temazepam)

3 . Endnotes

A. Flurazepam, estazolam, triazolam, and temazepam are only recommended for patients < 65 years old. These drugs were included on the American Geriatrics Society 2019 Beers Criteria update. [2] Flurazepam was removed in the 2023 AGS Beers Criteria update due to low utilization but is still considered potentially inappropriate in alignment with the 2019 AGS Beers Criteria. [3]

4 . References

1. Flurazepam Prescribing Information. Chartwell RX, LLC. Congers, NY. December 2023.
2. The 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694.
3. American Geriatrics Society 2023 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2023;1-30.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228428
Guideline Name	Fotivda (tivozanib) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Fotivda (tivozanib)
Renal cell carcinoma (RCC) Indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

2 . Criteria

Product Name:Fotivda	
Diagnosis	Renal cell carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FOTIVDA	TIVOZANIB HCL CAP 890 MCG (BASE EQUIVALENT)	21533076250120	Brand
FOTIVDA	TIVOZANIB HCL CAP 1340 MCG (BASE EQUIVALENT)	21533076250130	Brand

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma (RCC)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has received two or more prior systemic therapies (e.g., chemotherapy)

Product Name:Fotivda	
Diagnosis	Renal cell carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FOTIVDA	TIVOZANIB HCL CAP 890 MCG (BASE EQUIVALENT)	21533076250120	Brand
FOTIVDA	TIVOZANIB HCL CAP 1340 MCG (BASE EQUIVALENT)	21533076250130	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Fotivda	
Diagnosis	Renal cell carcinoma (RCC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
FOTIVDA	TIVOZANIB HCL CAP 890 MCG (BASE EQUIVALENT)	21533076250120	Brand
FOTIVDA	TIVOZANIB HCL CAP 1340 MCG (BASE EQUIVALENT)	21533076250130	Brand

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma (RCC)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has received two or more prior systemic therapies (e.g., chemotherapy)

3 . References

1. Fotivda Prescribing Information. AVEO Pharmaceuticals, Inc. Boston, MA. March 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed April 5, 2024.

Prior Authorization Guideline

Guideline ID	GL-233384
Guideline Name	Fruzaqla (fruquintinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	1/17/2024
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Fruzaqla (fruquintinib)
Metastatic colorectal cancer (mCRC) Indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine , oxaliplatin, and irinotecan based chemotherapy, an anti VEGF therapy, and, if RAS wild type and medically appropriate, an anti-EGFR therapy

2 . Criteria

Product Name:Fruzaqla	
Diagnosis	Metastatic colorectal cancer (mCRC)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FRUZAQLA	FRUQUINTINIB CAP 1 MG	21335035000120	Brand
FRUZAQLA	FRUQUINTINIB CAP 5 MG	21335035000140	Brand

Approval Criteria

1 - Diagnosis of metastatic colorectal cancer (mCRC)

AND

2 - Patient has been previously treated with both of the following:

- Fluoropyrimidine-, oxaliplatin-, irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI)
- Anti-VEGF biological therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])

AND

3 - One of the following:

3.1 Patient has RAS mutant tumors

OR

3.2 All of the following:

3.2.1 Patient has RAS wild-type tumors

AND

3.2.2 Patient has been previously treated with an anti-EGFR biological therapy (e.g., Vectibix [panitumumab], Erbitux [cetuximab])

AND

3.2.3 One of the following:

3.2.3.1 Trial and failure, contraindication or intolerance to Stivarga [regorafenib]

OR

3.2.3.2 For continuation of prior therapy

Product Name:Fruzaqla	
Diagnosis	Metastatic colorectal cancer (mCRC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FRUZAQLA	FRUQUINTINIB CAP 1 MG	21335035000120	Brand
FRUZAQLA	FRUQUINTINIB CAP 5 MG	21335035000140	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Fruzaqla Prescribing Information. Takeda Pharmaceuticals America, Inc., Lexington, MA. November 2023

4 . Revision History

Date	Notes
3/13/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-229174
Guideline Name	Furoscix (furosemide injection) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	12/14/2022
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Furoscix (furosemide injection)
Congestion Indicated for the treatment of congestion due to fluid overload in adults with chronic heart failure.

2 . Criteria

Product Name:Furoscix	
Approval Length	3 Month(s) [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FUROSCIX	FUROSEMIDE SUBCUTANEOUS CARTRIDGE KIT 80 MG/10ML	3720003000F720	Brand

Approval Criteria

1 - Diagnosis of chronic heart failure

AND

2 - Patient is currently on maintenance oral diuretic therapy (e.g., bumetanide, furosemide, torsemide) [C]

AND

3 - Provider attests that patient will be closely monitored for fluid, electrolyte, and metabolic abnormalities throughout therapy (e.g., hypokalemia, hypovolemia, hyponatremia) [B]

Product Name:Furoscix	
Approval Length	3 Month(s) [A]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
FUROSCIX	FUROSEMIDE SUBCUTANEOUS CARTRIDGE KIT 80 MG/10ML	3720003000F720	Brand

Approval Criteria

1 - Diagnosis of chronic heart failure

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming patient is currently on maintenance oral diuretic therapy (e.g., bumetanide, furosemide, torsemide) [C]

AND

3 - Provider attests that patient will be closely monitored for fluid, electrolyte, and metabolic abnormalities throughout therapy (e.g., hypokalemia, hypovolemia, hyponatremia) [B]

3 . Endnotes

A. Furoscix is not for chronic use and should be replaced with oral diuretics as soon as practical. [1]
B. Furosemide may cause fluid, electrolyte, and metabolic abnormalities such as hypovolemia, hypokalemia, azotemia, hyponatremia, hypochloremic alkalosis, hypomagnesemia, hypocalcemia, hyperglycemia, or hyperuricemia, particularly in patients receiving higher doses, patients with inadequate oral electrolyte intake, and in elderly patients. Serum electrolytes, CO , BUN, creatinine, glucose, and uric acid should be monitored frequently during furosemide therapy. [1]
C. Maintenance oral diuretic therapy includes those receiving 40-160 mg of oral furosemide equivalents daily (20-80 mg Torsemide or 1-4 mg Bumetanide). [3]

4 . References

1. Furoscix Prescribing Information. scPharmaceuticals, Inc. Burlington, MA. August 2024.
2. scPharmaceuticals, Inc. A Multicenter, Randomized, Open Label, Controlled Study Evaluating the Effectiveness and Safety of Furoscix On-Body Infusor vs Continued Medical Therapy for Worsening Heart Failure. clinicaltrials.gov. Published May 3, 2022.
3. scPharmaceuticals, Inc. Economic Impact of Reducing Hospital Admissions for Patients Presenting to the Emergency Department With Worsening Heart Failure: An Adaptive Clinical Trial of Furoscix Infusor. clinicaltrials.gov. Published July 9, 2021.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228429
Guideline Name	Fyarro (sirolimus albumin-bound particles for injectable suspension) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Fyarro (sirolimus albumin-bound particles for injectable suspension)
Perivascular Epithelioid Cell Tumor (PEComa) Indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

2 . Criteria

Product Name:Fyarro	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FYARRO	SIROLIMUS PROTEIN-BOUND PARTICLES FOR IV SUSP 100 MG	21532560201920	Brand

Approval Criteria

1 - Diagnosis of malignant perivascular epithelioid cell tumor

AND

2 - Disease is one of the following:

- Unresectable locally advanced
- Metastatic

AND

3 - One of the following:

3.1 Trial of or intolerance to one of the following [A]:

- Sirolimus
- Everolimus
- Temsirolimus

OR

3.2 For continuation of prior therapy

Product Name:Fyarro	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

FYARRO	SIROLIMUS PROTEIN-BOUND PARTICLES FOR IV SUSP 100 MG	21532560201920	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Fyarro	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
FYARRO	SIROLIMUS PROTEIN-BOUND PARTICLES FOR IV SUSP 100 MG	21532560201920	Brand

Approval Criteria

1 - Diagnosis of malignant perivascular epithelioid cell tumor

AND

2 - Disease is one of the following:

- Unresectable locally advanced
- Metastatic

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial of or intolerance to one of the following [A]:

- Sirolimus
- Everolimus

- Temsirolimus

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy, defined as no more than a 45-day gap in therapy

3 . Endnotes

A. mTOR inhibitors such as sirolimus, temsirolimus, and everolimus have shown promising results in patients with metastatic PEComas and are listed as other recommended regimens in NCCN (category 2A). [2]

4 . References

1. Fyarro Prescribing Information. Aadi Bioscience. Pacific Palisades, CA. November 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma v1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed May 4, 2022.

Prior Authorization Guideline

Guideline ID	GL-228864
Guideline Name	Galafold (migalastat)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Galafold (migalastat)
Fabry Disease Indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. This indication is approved based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2 . Criteria

Product Name:Galafold	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GALAFOLD	MIGALASTAT HCL CAP 123 MG (BASE EQUIVALENT)	30903650100120	Brand

Approval Criteria

1 - Diagnosis of Fabry Disease

AND

2 - One of the following: [3, 4]

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing
- Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

3 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data [A]

AND

4 - Will not be used in combination with other drugs used for Fabry disease [B]

Product Name:Galafold	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

GALAFOLD	MIGALASTAT HCL CAP 123 MG (BASE EQUIVALENT)	30903650100120	Brand

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by one of the following: [3, 4]

- Reduction in plasma or urinary sediment lyso-GL-3, GL-3 compared to baseline
- Reduction in number of GL-3 inclusions per kidney interstitial capillary (KIC) in renal biopsy samples compared to baseline
- Improvement and/or stabilization in symptoms (e.g., renal function, neuropathic pain)

AND

2 - Will not be used in combination with other drugs used for Fabry disease [B]

3 . Endnotes

A. In an in vitro assay (HEK-293 assay), Human Embryonic Kidney (HEK-293) cell lines were transfected with specific GLA variants (mutations) which produced mutant alpha-Gal A proteins. A GLA variant was categorized as amenable if the resultant mutant alpha-Gal A activity (measured in the cell lysates) met two criteria: 1) it showed a relative increase of at least 20% compared to the pre-treatment alpha-Gal A activity, and 2) it showed an absolute increase of at least 3% of the wild-type (normal) alpha-Gal A activity. Whether a certain amenable GLA variant in a patient with Fabry disease is disease-causing or not should be determined by the prescribing physician (in consultation with a clinical genetics professional, if needed) prior to treatment initiation. [1]
B. The safety and effectiveness of concomitant use of Galafold and Fabrazyme (agalsidase beta) has not been established. [2]

4 . References

1. Galafold prescribing information. Amicus Therapeutics U.S., Inc. Cranbury, NJ. June 2023.
2. Per clinical consultation with geneticist. October 11, 2018.
3. Ortiz A, Germain DP, Desnick RJ, et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab. 2018;123(4):416-427. doi:10.1016/j.ymgme.2018.02.014.

4. Michaud M, Mauhin W, Belmatoug N, et al. When and How to Diagnose Fabry Disease in Clinical Pratice. Am J Med Sci. 2020;360(6):641-649. doi:10.1016/j.amjms.2020.07.011.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Gamifant (emapalumab-lzsg)

Prior Authorization Guideline

Guideline ID	GL-228865
Guideline Name	Gamifant (emapalumab-lzsg)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Gamifant (emapalumab-lzsg)
Primary Hemophagocytic Lymphohistiocytosis (HLH) Indicated for the treatment of adult and pediatric (newborn and older) patients with primary HLH with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

2 . Criteria

Product Name:Gamifant	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 10 MG/2ML	99405035402020	Brand
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 50 MG/10ML	99405035402040	Brand
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 100 MG/20ML	99405035402060	Brand

Approval Criteria

1 - Diagnosis of primary hemophagocytic lymphohistiocytosis (HLH)

AND

2 - One of the following:

2.1 Disease is one of the following:

- Refractory
- Recurrent
- Progressive

OR

2.2 Trial and failure, contraindication, or intolerance to conventional HLH therapy (e.g., etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Patient has not received hematopoietic stem cell transplantation (HSCT)

Product Name:Gamifant

Approval Length	6 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 10 MG/2ML	99405035402020	Brand
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 50 MG/10ML	99405035402040	Brand
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 100 MG/20ML	99405035402060	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers)

AND

2 - Patient has not received HSCT

3 . Endnotes

A. Per clinical consultation, it is appropriate to limit authorization duration to no more than 6 months at a time, given that the ultimate goal in therapy is to receive HSCT and treatment with Gamifant should be viewed as bridge therapy to HSCT. Pivotal trial data duration was also less than 3 months. [2]

4 . References

1. Gamifant Prescribing Information. Sobi Inc. Waltham, MA. June 2020.
2. Per clinical consult with a pediatric hematologist/oncologist, January 18, 2019.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233373
Guideline Name	Gattex (teduglutide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	2/19/2013
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Gattex (teduglutide)
Short Bowel Syndrome (SBS) Indicated for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

2 . Criteria

Product Name:Gattex	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GATTEX	TEDUGLUTIDE (RDNA) FOR INJ KIT 5 MG	52533070006420	Brand

Approval Criteria

1 - Diagnosis of short bowel syndrome

AND

2 - Patient is 1 year of age and older

AND

3 - Documentation that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 consecutive months [A]

AND

4 - Prescribed by or in consultation with a gastroenterologist [C]

Product Name:Gattex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GATTEX	TEDUGLUTIDE (RDNA) FOR INJ KIT 5 MG	52533070006420	Brand

Approval Criteria

1 - Documentation that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on Gattex therapy [B]

AND

2 - Prescribed by or in consultation with a gastroenterologist [C]

3 . Endnotes

A. Twelve consecutive months on parenteral nutrition is an inclusion criterion in clinical trials. [1]
B. In clinical trial data, treatment with Gattex has been shown to reduce the volume and number of days that patients with short bowel syndrome require parenteral nutrition/intravenous (PN/IV) support, with some patients remaining on Gattex therapy even if PN/IV support was no longer required. [1, 6-8]
C. Patients with short bowel syndrome (SBS) have undergone one or more surgical bowel resections due to underlying disease, congenital defects, or other trauma. These resections lead to inadequate digestion and absorption, requiring patients to become dependent on parenteral nutrition and/or intravenous (PN/IV) support. The management of PN/IV is complex and must be individualized to each patient as the degree of malabsorption can vary among patients with SBS. Long-term use of PN/IV can often lead to other complications, such as bacterial infections, blood clots, gallbladder disease, and liver and kidney problems. For SBS patients on chronic PN/IV, the goal of treatment is to reduce the need for PN/IV in order to improve the patients' quality of life and reduce the risk of any life-threatening complications. Careful monitoring of patients treated with Gattex is recommended in order to assess continued safety and manage any adverse effects or complications. [1-7]

4 . References

1. Gattex Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. October 2022.
2. Van Gossum A, Cabre E, Hébuterne X, et al. ESPEN Guidelines on Parenteral Nutrition: gastroenterology. Clin Nutr. 2009;28(4):415-27.
3. Nightingale J, Woodward JM on behalf of the Small Bowel and Nutrition Committee of the British Society of Gastroenterology. Guidelines for management of patients with a short bowel. Gut. 2006;55(Suppl 4):iv1-12.
4. National Institute of Diabetes and Digestive and Kidney Diseases. Short Bowel Syndrome. https://www.niddk.nih.gov/health-information/digestive-diseases/short-bowel-syndrome. Accessed December 7, 2020.

5. Buchman AL, Scolapio J, Fryer J. AGA technical review on short bowel syndrome and intestinal transplantation. Gastroenterology. 2003;124(4):1111-34.
6. Jeppesen PB, Pertkiewicz M, Messing B, et al. Teduglutide reduces need for parenteral support among patients with short bowel syndrome with intestinal failure. Gastroenterology. 2012;143(6):1473-1481.
7. Seidner DL, Schwartz LK, Winkler MF, Jeejeebhoy K, Boullata JI, Tappenden KA. Increased intestinal absorption in the era of teduglutide and its impact on management strategies in patients with short bowel syndrome-associated intestinal failure. J Parenter Enteral Nutr. 2013;37(2):201-11.
8. Naberhuis JK, Tappenden KA. Teduglutide for safe reduction of parenteral nutrient and/or fluid requirements in adults: a systematic review. J Parenter Enteral Nutr. 2016;40(8):1096-1105.
9. DiBaise, J. UptoDate. Management of the short bowel syndrome in adults. November 2022. Available at: https://www.uptodate.com/contents/management-of-the-short-bowel-syndrome-in-adults?search=GATTEX&source=search_result&selectedTitle=2~8&usage_type=default&display_rank=1. Accessed December 30, 2022.
10. Stamm, D., Duggan, C. UptoDate. Management of short bowel syndrome in children. November 2022. Available at: https://www.uptodate.com/contents/management-of-short-bowel-syndrome-in-children?search=GATTEX&source=search_result&selectedTitle=3~8&usage_type=default&display_rank=2. Accessed December 30, 2022.
11. Iyer, K., DiBaise, J., et al. AGA Clinical Practice Update on Management of Short Bowel Syndrome: Expert Review. June 2022. Available at: https://www.cghjournal.org/article/S1542-3565(22)00561-4/fulltext#pageBody. Accessed December 30, 2022.

5 . Revision History

Date	Notes
3/6/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-233316
Guideline Name	Gaucher Disease Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/17/2025
P&T Approval Date:	11/20/2000
P&T Revision Date:	11/21/2024 ; 11/21/2024

1 . Indications

Drug Name: Cerezyme (imiglucerase for injection)
Type 1 Gaucher Disease Indicated for treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions: - anemia - thrombocytopenia - bone disease - hepatomegaly or splenomegaly
Drug Name: Elelyso (taliglucerase alfa) for injection
Type 1 Gaucher Disease Indicated for the treatment of patients 4 years and older with a confirmed diagnosis of Type 1 Gaucher disease.
Drug Name: VPRIV (velaglucerase alfa for injection)
Type 1 Gaucher Disease Indicated for long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease.

Drug Name: Cerdelga (eliglustat)
Type 1 Gaucher Disease Indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test. Limitations of Use: Patients who are CYP2D6 ultra-rapid metabolizers (URMs) may not achieve adequate concentrations of CERDELGA to achieve a therapeutic effect. A specific dosage cannot be recommended for those patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers).

Drug Name: Zavesca (miglustat), Yargesa (miglustat)
Type 1 Gaucher Disease Indicated as monotherapy for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to allergy, hypersensitivity, or poor venous access).

2 . Criteria

Product Name:Cerezyme, Elelyso, or VPRIV	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CEREZYME	IMIGLUCERASE FOR INJ 400 UNIT	82700050002120	Brand
VPRIV	VELAGLUCERASE ALFA FOR INJ 400 UNIT	82700085102120	Brand
ELELYSO	TALIGLUCERASE ALFA FOR INJ 200 UNIT	82700080102120	Brand

Approval Criteria

1 - Diagnosis of Type 1 Gaucher disease

AND

2 - Patient has evidence of symptomatic disease (e.g., moderate to severe anemia [A], thrombocytopenia [B], bone disease [C], hepatomegaly [D], or splenomegaly [D])

AND

3 - One of the following:

3.1 Patient is 4 years of age or older (applies to Elelyso and VPRIV only)

OR

3.2 Patient is 2 years of age or older (applies to Cerezyme only)

Product Name:Cerdelga	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CERDELGA	ELIGLUSTAT TARTRATE CAP 84 MG (BASE EQUIVALENT)	82700040600120	Brand

Approval Criteria

1 - Diagnosis of Type 1 Gaucher disease

AND

2 - Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test

AND

3 - Patient is 18 years of age or older

Product Name:Brand Zavesca, Generic miglustat, or Yargesa	
Diagnosis	Type 1 Gaucher Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZAVESCA	MIGLUSTAT CAP 100 MG	82700070000120	Brand
MIGLUSTAT	MIGLUSTAT CAP 100 MG	82700070000120	Generic
YARGESA	MIGLUSTAT CAP 100 MG	82700070000120	Generic

Approval Criteria

1 - Diagnosis of mild to moderate Type 1 Gaucher disease

AND

2 - Patient is 18 years of age or older

Product Name:Brand Zavesca, Generic miglustat	
Diagnosis	Niemann-Pick disease type C (NPC) (off-label) [E]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MIGLUSTAT	MIGLUSTAT CAP 100 MG	82700070000120	Generic
ZAVESCA	MIGLUSTAT CAP 100 MG	82700070000120	Brand

Approval Criteria

1 - Diagnosis of Niemann-Pick disease type C (NPC)

AND

2 - Requested drug will be used in combination with Miplyffa (arimoclomol)

AND

3 - Prescribed by or in consultation with a specialist knowledgeable in the treatment of Niemann-Pick disease type C

Product Name:Brand Zavesca, Generic miglustat	
Diagnosis	Niemann-Pick disease type C (NPC) (off-label) [E]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MIGLUSTAT	MIGLUSTAT CAP 100 MG	82700070000120	Generic
ZAVESCA	MIGLUSTAT CAP 100 MG	82700070000120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Requested drug will be used in combination with Miplyffa (arimoclomol)

3 . Endnotes

A. Goals of treatment with anemia are to increase hemoglobin to greater than or equal to 12.0 g/dL for males (greater than 12 years of age), and to greater than or equal to 11.0

g/dL for both children (less than or equal to 12 years of age) and females (greater than 12 years of age). [6, 8]

B. Moderate thrombocytopenia is defined as a platelet count of 60,000 to 120,000/microliter. A platelet count of 120,000/microliter to meet the criterion of thrombocytopenia is based on the upper end of the range that defines moderate thrombocytopenia. [6]
C. In bone disease, the goal is to lessen or eliminate bone pain and prevent bone crises. Bone disease can be diagnosed using MRI, bone scan, and X-ray. [6-8]
D. Hepatomegaly is defined as a liver mass of greater than 1.25 times normal value. Splenomegaly is defined as a splenic mass greater than the normal, and moderate splenomegaly is considered a spleen volume of greater than 5 and less than or equal to 15 times normal. [6]
E. Criteria is here to support the off-label use of miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in combination with Miplyffa as per Miplyffa FDA labelling. [12-14]

4 . References

1. Cerezyme Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2022.
2. Elelyso Prescribing Information. Pfizer, Inc. New York, NY. May 2023.
3. VPRIV Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA. September 2021.
4. Cerdelga Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2023.
5. Zavesca Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. August 2022.
6. Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic goals in the treatment of Gaucher disease. Semin Hematol. 2004;41(4 Suppl 5):4-14.
7. Weinreb NJ, Aggio MC, Andersson HC, et al. Gaucher disease type 1: revised recommendations on evaluations and monitoring for adult patients. Semin Hematol. 2004;41(suppl 5):15-22.
8. Weinreb N, Taylor J, Cox T, et al. A benchmark analysis of the achievement of therapeutic goals for type 1 Gaucher disease patients treated with imiglucerase. Am J Hematol. 2008;83:890-895.
9. Hollak CE, vom Dahl S, Aerts JM, et al. Force majeure: therapeutic measures in response to restricted supply of imiglucerase (Cerezyme) for patients with Gaucher disease. Blood Cells Mol Dis. 2010;44(1):41-7.
10. Per clinical consult with geneticist, November 11, 2010.
11. Yargesa Prescribing Information. Edenbridge Pharmaceuticals LLC. Parsippany, NJ. October 2023.
12. Miplyffa Prescribing Information. Zevra Therapeutics, Inc. FL 34747. September 2024.
13. Mengel E, Patterson MC, Da Riol RM et al. Efficacy and safety of arimoclomol in Niemann-Pick disease type C: Results from a double-blind, randomised, placebo-controlled, multinational phase 2/3 trial of a novel treatment. J Inherit Metab Dis. 2021 Nov;44(6):1463-1480. doi: 10.1002/jimd.12428. Epub 2021 Sep 7.
14. FDA Review: Miplyffa. Food and Drug Administration Web Site. 2024. http://www.accessdata.fda.gov. Accessed November 4, 2024.

5 . Revision History

Date	Notes
1/16/2025	Criteria updated

Gavreto (pralsetinib)

Prior Authorization Guideline

Guideline ID	GL-229157
Guideline Name	Gavreto (pralsetinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/12/2020
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Gavreto (pralsetinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test. **RET Fusion-Positive Thyroid Cancer** Indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate) This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name:Gavreto	
Diagnosis	Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAVRETO	PRALSETINIB CAP 100 MG	21535750000120	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s) as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Gavreto	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAVRETO	PRALSETINIB CAP 100 MG	21535750000120	Brand

Approval Criteria

1 - Diagnosis of thyroid cancer

AND

2 - Disease is one of the following:

- Advanced
- Metastatic

AND

3 - Presence of rearranged during transfection (RET) gene fusion-positive tumor(s)

AND

4 - Patient is 12 years of age or older

AND

5 - Disease requires treatment with systemic therapy

AND

6 - ONE of the following :

- Patient is radioactive iodine-refractory
- Radioactive iodine therapy is not appropriate

Product Name:Gavreto	
Diagnosis	Lung Cancer, Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAVRETO	PRALSETINIB CAP 100 MG	21535750000120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Gavreto Prescribing Information. Blueprint Medicines Corporation. Cambridge, MA. March 2024.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228432
Guideline Name	Gazyva (obinutuzumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Gazyva (obinutuzumab)
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL) in combination with chlorambucil. **Follicular Lymphoma (FL)** 1) Indicated in combination with bendamustine followed by Gazyva monotherapy for the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to, a rituximab-containing regimen. 2) Indicated for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma in combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission. **Off Label Uses: Small Lymphocytic Lymphoma (SLL) [2]**

2 . Criteria

Product Name:Gazyva	
Diagnosis	Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Leukemia (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAZYVA	OBINUTUZUMAB SOLN FOR IV INFUSION 1000 MG/40ML (25 MG/ML)	21351843002025	Brand

Approval Criteria

1 - One of the following:

- Diagnosis of chronic lymphocytic leukemia (CLL) and is previously untreated for CLL
- Diagnosis of small lymphocytic leukemia (SLL) and previously untreated for SLL [A]

AND

2 - Used in combination with chlorambucil [2,3]

Product Name:Gazyva	
Diagnosis	Follicular Lymphoma (FL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAZYVA	OBINUTUZUMAB SOLN FOR IV INFUSION 1000 MG/40ML (25 MG/ML)	21351843002025	Brand

Approval Criteria

1 - Diagnosis of follicular lymphoma (FL)

AND

2 - One of the following:

2.1 All of the following:

2.1.1 Relapsed or refractory to a rituximab-containing regimen [B]

AND

2.1.2 Will be used in combination with bendamustine for six cycles prior to maintenance treatment with Gazyva monotherapy

OR

2.2 All of the following:

2.2.1 Diagnosis of stage II bulky, III or IV follicular lymphoma

AND

2.2.2 Patient has not been treated with prior therapy

AND

2.2.3 Both of the following:

- Used in combination with chemotherapy until at least partial remission has been achieved
- Followed by Gazyva monotherapy

Product Name:Gazyva	
Diagnosis	All Indications

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAZYVA	OBINUTUZUMAB SOLN FOR IV INFUSION 1000 MG/40ML (25 MG/ML)	21351843002025	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. The National Comprehensive Cancer Network (NCCN) guidelines support the use of obinutuzumab for the treatment of small lymphocytic leukemia (SLL). One clinical trial showed the combination of obinutuzumab plus chlorambucil resulted in significant improvement in the median progression free survival (PFS) compared to chlorambucil alone (26.7 months vs 11.1 months, respectively). [2]
B. NCCN supports use of obinutuzumab in the treatment of follicular lymphoma as maintenance therapy for rituximab refractory disease in patients with indications for treatment as second-line extended dosing. [2]

4 . References

1. Gazyva Prescribing Information, Genentech Inc. San Francisco, CA. July 2022.
2. NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 25, 2024.
3. National Comprehensive Cancer Network(NCCN) Practice Guidelines in Oncology. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma v2.2024. Available at: https://www.nccn.org/professionals/physician_gls/ pdf/cll.pdf. Accessed March 25, 2024.
4. Sharman JP, Banerji V, Fogliatto LM, et al. ELEVATE TN: Phase 3 study of acalabrutinib combined with obinutuzumab (O) or alone vs O plus chlorambucil (Clb) in patients (Pts) with treatment-naïve chronic lymphocytic leukemia (CLL). Blood. 2019;134 (Supplement_1):31.

Prior Authorization Guideline

Guideline ID	GL-233335
Guideline Name	Generic-First Step Program
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/18/2025
P&T Approval Date:	11/14/2019
P&T Revision Date:	1/18/2024

1 . Criteria

Product Name:Brand contraceptive drug which has a generic counterpart	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
GENERESS FE	NORETHINDRONE & ETHINYL ESTRADIOL-FE CHEW TAB 0.8 MG-25 MCG	25990003600540	Brand
LOESTRIN 1/20-21	NORETHINDRONE ACE & ETHINYL ESTRADIOL TAB 1 MG-20 MCG	25990002600310	Brand

LOESTRIN 1.5/30-21	NORETHINDRONE ACE & ETHINYL ESTRADIOL TAB 1.5 MG-30 MCG	25990002600320	Brand
LOESTRIN FE 1/20	NORETHINDRONE ACE & ETHINYL ESTRADIOL-FE TAB 1 MG-20 MCG	25990003610310	Brand
LOESTRIN FE 1.5/30	NORETHINDRONE ACE & ETHINYL ESTRADIOL-FE TAB 1.5 MG-30 MCG	25990003610320	Brand
SAFYRAL	DROSPIRENONE-ETHINYL ESTRAD-LEVOMEFOLATE TAB 3-0.03-0.451 MG	25990003200330	Brand
SEASONIQUE	LEVONORG-ETH EST TAB 0.15-0.03MG(84) & ETH EST TAB 0.01MG(7)	25993002300330	Brand
YASMIN 28	DROSPIRENONE-ETHINYL ESTRADIOL TAB 3-0.03 MG	25990002150320	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Patient is using the prescribed drug for contraception or other FDA-approved condition*
- The requested product is medically necessary**

OR

1.2 Both of the following:

- Patient is using the prescribed drug for contraception or other FDA-approved condition*
- Trial and failure of a minimum 30 day supply, or intolerance to target's generic counterpart

Notes	*Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmennorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner's syndrome; (17) Uterine fibroids or adenomyosis. **An

	y justification of medical necessity/appropriateness provided by the pr escriber is adequate to approve access.

Product Name:Brand drug which has a generic counterpart	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ALTACE	RAMIPRIL CAP 1.25 MG	36100050000110	Brand
ALTACE	RAMIPRIL CAP 2.5 MG	36100050000120	Brand
ALTACE	RAMIPRIL CAP 5 MG	36100050000130	Brand
ALTACE	RAMIPRIL CAP 10 MG	36100050000140	Brand
ABILIFY	ARIPIPRAZOLE TAB 2 MG	59250015000305	Brand
ABILIFY	ARIPIPRAZOLE TAB 5 MG	59250015000310	Brand
ABILIFY	ARIPIPRAZOLE TAB 10 MG	59250015000320	Brand
ABILIFY	ARIPIPRAZOLE TAB 15 MG	59250015000330	Brand
ABILIFY	ARIPIPRAZOLE TAB 20 MG	59250015000340	Brand
ABILIFY	ARIPIPRAZOLE TAB 30 MG	59250015000350	Brand
ARTHROTEC 75	DICLOFENAC W/ MISOPROSTOL TAB DELAYED RELEASE 75-0.2 MG	66109902200630	Brand
ATACAND	CANDESARTAN CILEXETIL TAB 4 MG	36150020100310	Brand
ATACAND	CANDESARTAN CILEXETIL TAB 8 MG	36150020100320	Brand
ATACAND	CANDESARTAN CILEXETIL TAB 16 MG	36150020100330	Brand
ATACAND	CANDESARTAN CILEXETIL TAB 32 MG	36150020100340	Brand
AVAPRO	IRBESARTAN TAB 75 MG	36150030000310	Brand
AVAPRO	IRBESARTAN TAB 150 MG	36150030000320	Brand
AVAPRO	IRBESARTAN TAB 300 MG	36150030000340	Brand
CANASA	MESALAMINE SUPPOS 1000 MG	52500030005240	Brand
CARBATROL	CARBAMAZEPINE CAP ER 12HR 100 MG	72600020006910	Brand
CARBATROL	CARBAMAZEPINE CAP ER 12HR 200 MG	72600020006920	Brand
CARBATROL	CARBAMAZEPINE CAP ER 12HR 300 MG	72600020006930	Brand
CARNITOR	LEVOCARNITINE TAB 330 MG	30903045100330	Brand
CARNITOR	LEVOCARNITINE ORAL SOLN 1 GM/10ML (10%)	30903045102010	Brand

CARNITOR SF	LEVOCARNITINE ORAL SOLN 1 GM/10ML (10%)	30903045102010	Brand
CATAPRES-TTS-1	CLONIDINE TD PATCH WEEKLY 0.1 MG/24HR	36201010008810	Brand
CATAPRES-TTS-2	CLONIDINE TD PATCH WEEKLY 0.2 MG/24HR	36201010008820	Brand
CATAPRES-TTS-3	CLONIDINE TD PATCH WEEKLY 0.3 MG/24HR	36201010008830	Brand
CELEXA	CITALOPRAM HYDROBROMIDE TAB 10 MG (BASE EQUIV)	58160020100310	Brand
CELEXA	CITALOPRAM HYDROBROMIDE TAB 20 MG (BASE EQUIV)	58160020100320	Brand
CELEXA	CITALOPRAM HYDROBROMIDE TAB 40 MG (BASE EQUIV)	58160020100340	Brand
CIALIS	TADALAFIL TAB 2.5 MG	40304080000302	Brand
CIALIS	TADALAFIL TAB 5 MG	40304080000305	Brand
CLARINEX	DESLORATADINE TAB 5 MG	41550021000320	Brand
CLIMARA	ESTRADIOL TD PATCH WEEKLY 0.025 MG/24HR	24000035008810	Brand
CLIMARA	ESTRADIOL TD PATCH WEEKLY 0.0375 MG/24HR (37.5 MCG/24HR)	24000035008815	Brand
CLIMARA	ESTRADIOL TD PATCH WEEKLY 0.05 MG/24HR	24000035008820	Brand
CLIMARA	ESTRADIOL TD PATCH WEEKLY 0.06 MG/24HR	24000035008824	Brand
CLIMARA	ESTRADIOL TD PATCH WEEKLY 0.075 MG/24HR	24000035008830	Brand
CLIMARA	ESTRADIOL TD PATCH WEEKLY 0.1 MG/24HR	24000035008840	Brand
CLOBEX	CLOBETASOL PROPIONATE SPRAY 0.05%	90550025100910	Brand
CLOBEX	CLOBETASOL PROPIONATE LOTION 0.05%	90550025104110	Brand
CLOBEX	CLOBETASOL PROPIONATE SHAMPOO 0.05%	90550025104520	Brand
COLESTID	COLESTIPOL HCL TAB 1 GM	39100020100320	Brand
COLESTID	COLESTIPOL HCL GRANULES 5 GM	39100020102705	Brand
COLESTID FLAVORED	COLESTIPOL HCL GRANULES 5 GM	39100020102705	Brand
COLESTID	COLESTIPOL HCL GRANULE PACKETS 5 GM	39100020103010	Brand
COLESTID FLAVORED	COLESTIPOL HCL GRANULE PACKETS 5 GM	39100020103010	Brand
COREG	CARVEDILOL TAB 3.125 MG	33300007000305	Brand

COREG	CARVEDILOL TAB 6.25 MG	33300007000310	Brand
COREG	CARVEDILOL TAB 12.5 MG	33300007000320	Brand
COREG	CARVEDILOL TAB 25 MG	33300007000330	Brand
COREG CR	CARVEDILOL PHOSPHATE CAP ER 24HR 10 MG	33300007207010	Brand
COREG CR	CARVEDILOL PHOSPHATE CAP ER 24HR 20 MG	33300007207020	Brand
COREG CR	CARVEDILOL PHOSPHATE CAP ER 24HR 40 MG	33300007207030	Brand
COREG CR	CARVEDILOL PHOSPHATE CAP ER 24HR 80 MG	33300007207050	Brand
CORTEF	HYDROCORTISONE TAB 5 MG	22100025000303	Brand
CORTEF	HYDROCORTISONE TAB 10 MG	22100025000305	Brand
CORTEF	HYDROCORTISONE TAB 20 MG	22100025000310	Brand
COSOPT	DORZOLAMIDE HCL-TIMOLOL MALEATE OPHTH SOLN 22.3-6.8 MG/ML	86259902202020	Brand
COSOPT PF	DORZOLAMIDE HCL-TIMOLOL MALEATE OPHTH SOL 22.3-6.8 MG/ML PF	86259902202060	Brand
COZAAR	LOSARTAN POTASSIUM TAB 25 MG	36150040200320	Brand
COZAAR	LOSARTAN POTASSIUM TAB 50 MG	36150040200330	Brand
COZAAR	LOSARTAN POTASSIUM TAB 100 MG	36150040200340	Brand
DELESTROGEN	ESTRADIOL VALERATE IM IN OIL 20 MG/ML	24000035201710	Brand
DELESTROGEN	ESTRADIOL VALERATE IM IN OIL 40 MG/ML	24000035201715	Brand
DEPAKOTE SPRINKLES	DIVALPROEX SODIUM CAP DELAYED RELEASE SPRINKLE 125 MG	7250001010H120	Brand
DEPAKOTE ER	DIVALPROEX SODIUM TAB ER 24 HR 250 MG	72500010107520	Brand
DEPAKOTE ER	DIVALPROEX SODIUM TAB ER 24 HR 500 MG	72500010107530	Brand
EPIDUO	ADAPALENE-BENZOYL PEROXIDE GEL 0.1-2.5%	90059902034020	Brand
ESTRACE	ESTRADIOL TAB 0.5 MG	24000035000303	Brand
ESTRACE	ESTRADIOL TAB 1 MG	24000035000305	Brand
ESTRACE	ESTRADIOL TAB 2 MG	24000035000310	Brand
ESTRACE	ESTRADIOL VAGINAL CREAM 0.1 MG/GM	55350020003705	Brand
EXFORGE	AMLODIPINE BESYLATE-VALSARTAN TAB 5-160 MG	36993002100310	Brand

EXFORGE	AMLODIPINE BESYLATE-VALSARTAN TAB 5-320 MG	36993002100320	Brand
EXFORGE	AMLODIPINE BESYLATE-VALSARTAN TAB 10-160 MG	36993002100330	Brand
EXFORGE	AMLODIPINE BESYLATE-VALSARTAN TAB 10-320 MG	36993002100340	Brand
FIORICET	BUTALBITAL-ACETAMINOPHEN-CAFFEINE CAP 50-300-40 MG	64991003100108	Brand
FIORICET/CODEINE	BUTALBITAL-ACETAMINOPHEN-CAFF W/ COD CAP 50-300-40-30 MG	65991004100113	Brand
FLOMAX	TAMSULOSIN HCL CAP 0.4 MG	56852070100110	Brand
HYZAAR	LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE TAB 50-12.5 MG	36994002450320	Brand
HYZAAR	LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE TAB 100-12.5 MG	36994002450325	Brand
HYZAAR	LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE TAB 100-25 MG	36994002450340	Brand
IMITREX	SUMATRIPTAN NASAL SPRAY 5 MG/ACT	67406070002010	Brand
IMITREX	SUMATRIPTAN NASAL SPRAY 20 MG/ACT	67406070002040	Brand
IMITREX STATDOSE SYSTEM	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 4 MG/0.5ML	6740607010D510	Brand
IMITREX STATDOSE SYSTEM	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 6 MG/0.5ML	6740607010D520	Brand
IMITREX STATDOSE REFILL	SUMATRIPTAN SUCCINATE SOLUTION CARTRIDGE 4 MG/0.5ML	6740607010E210	Brand
IMITREX STATDOSE REFILL	SUMATRIPTAN SUCCINATE SOLUTION CARTRIDGE 6 MG/0.5ML	6740607010E220	Brand
IMITREX	SUMATRIPTAN SUCCINATE TAB 25 MG	67406070100305	Brand
IMITREX	SUMATRIPTAN SUCCINATE TAB 50 MG	67406070100310	Brand
IMITREX	SUMATRIPTAN SUCCINATE TAB 100 MG	67406070100320	Brand
IMITREX	SUMATRIPTAN SUCCINATE INJ 6 MG/0.5ML	67406070102010	Brand
KEPPRA	LEVETIRACETAM TAB 250 MG	72600043000320	Brand
KEPPRA	LEVETIRACETAM TAB 500 MG	72600043000330	Brand
KEPPRA	LEVETIRACETAM TAB 750 MG	72600043000340	Brand
KEPPRA	LEVETIRACETAM TAB 1000 MG	72600043000350	Brand
KEPPRA	LEVETIRACETAM ORAL SOLN 100 MG/ML	72600043002020	Brand
KEPPRA XR	LEVETIRACETAM TAB ER 24HR 500 MG	72600043007520	Brand
KEPPRA XR	LEVETIRACETAM TAB ER 24HR 750 MG	72600043007530	Brand

KLONOPIN	CLONAZEPAM TAB 0.5 MG	72100010000305	Brand
KLONOPIN	CLONAZEPAM TAB 1 MG	72100010000310	Brand
KLONOPIN	CLONAZEPAM TAB 2 MG	72100010000315	Brand
K-TAB	POTASSIUM CHLORIDE TAB ER 8 MEQ (600 MG)	79700030000420	Brand
K-TAB	POTASSIUM CHLORIDE TAB ER 10 MEQ	79700030000430	Brand
K-TAB	POTASSIUM CHLORIDE TAB ER 20 MEQ (1500 MG)	79700030000445	Brand
LAMICTAL	LAMOTRIGINE TAB 25 MG	72600040000310	Brand
LAMICTAL	LAMOTRIGINE TAB 100 MG	72600040000330	Brand
LAMICTAL	LAMOTRIGINE TAB 150 MG	72600040000335	Brand
LAMICTAL	LAMOTRIGINE TAB 200 MG	72600040000340	Brand
LAMICTAL CHEWABLE DISPERSIBLE	LAMOTRIGINE TAB CHEWABLE DISPERSIBLE 5 MG	72600040000510	Brand
LAMICTAL CHEWABLE DISPERSIBLE	LAMOTRIGINE TAB CHEWABLE DISPERSIBLE 25 MG	72600040000520	Brand
LAMICTAL STARTER/TAKING VALPROATE	LAMOTRIGINE TAB 25 MG (35) STARTER KIT	72600040006420	Brand
LAMICTAL STARTER/NOT TAKING CARBAMAZEPINE	LAMOTRIGINE TAB 25 MG (42) & 100 MG (7) STARTER KIT	72600040006430	Brand
LAMICTAL STARTER/TAKING CARBAMAZEPINE/NOT TAKING VALPROATE	LAMOTRIGINE TAB 25 MG (84) & 100 MG (14) STARTER KIT	72600040006435	Brand
LAMICTAL ODT	LAMOTRIGINE TAB DISINT 25 MG (21) & 50 MG (7) TITRATION KIT	72600040006450	Brand
LAMICTAL ODT	LAMOTRIGINE TAB DISINT 50 MG (42)-100 MG(14) TITRATION KIT	72600040006455	Brand
LAMICTAL ODT	LAMOTRIGINE TAB DISINT 25 (14) & 50 MG (14) & 100 MG (7) KIT	72600040006460	Brand
LAMICTAL ODT	LAMOTRIGINE ORALLY DISINTEGRATING TAB 25 MG	72600040007225	Brand
LAMICTAL ODT	LAMOTRIGINE ORALLY DISINTEGRATING TAB 50 MG	72600040007230	Brand
LAMICTAL ODT	LAMOTRIGINE ORALLY DISINTEGRATING TAB 100 MG	72600040007240	Brand
LAMICTAL ODT	LAMOTRIGINE ORALLY DISINTEGRATING TAB 200 MG	72600040007250	Brand
LAMICTAL XR	LAMOTRIGINE TAB ER 24HR 25 MG	72600040007510	Brand
LAMICTAL XR	LAMOTRIGINE TAB ER 24HR 50 MG	72600040007520	Brand

LAMICTAL XR	LAMOTRIGINE TAB ER 24HR 100 MG	72600040007530	Brand
LAMICTAL XR	LAMOTRIGINE TAB ER 24HR 200 MG	72600040007540	Brand
LAMICTAL XR	LAMOTRIGINE TAB ER 24HR 250 MG	72600040007545	Brand
LAMICTAL XR	LAMOTRIGINE TAB ER 24HR 300 MG	72600040007550	Brand
LASIX	FUROSEMIDE TAB 20 MG	37200030000305	Brand
LASIX	FUROSEMIDE TAB 40 MG	37200030000310	Brand
LASIX	FUROSEMIDE TAB 80 MG	37200030000315	Brand
LOTREL	AMLODIPINE BESYLATE-BENAZEPRIL HCL CAP 5-10 MG	36991502200130	Brand
LOTREL	AMLODIPINE BESYLATE-BENAZEPRIL HCL CAP 5-20 MG	36991502200140	Brand
LOTREL	AMLODIPINE BESYLATE-BENAZEPRIL HCL CAP 10-20 MG	36991502200150	Brand
LOTREL	AMLODIPINE BESYLATE-BENAZEPRIL HCL CAP 10-40 MG	36991502200160	Brand
LYRICA	PREGABALIN CAP 25 MG	72600057000110	Brand
LYRICA	PREGABALIN CAP 50 MG	72600057000115	Brand
LYRICA	PREGABALIN CAP 75 MG	72600057000120	Brand
LYRICA	PREGABALIN CAP 100 MG	72600057000125	Brand
LYRICA	PREGABALIN CAP 150 MG	72600057000135	Brand
LYRICA	PREGABALIN CAP 200 MG	72600057000145	Brand
LYRICA	PREGABALIN CAP 225 MG	72600057000150	Brand
LYRICA	PREGABALIN CAP 300 MG	72600057000160	Brand
LYRICA	PREGABALIN SOLN 20 MG/ML	72600057002020	Brand
MAXALT	RIZATRIPTAN BENZOATE TAB 10 MG (BASE EQUIVALENT)	67406060100320	Brand
MAXALT-MLT	RIZATRIPTAN BENZOATE ORAL DISINTEGRATING TAB 10 MG (BASE EQ)	67406060107230	Brand
MICARDIS	TELMISARTAN TAB 20 MG	36150070000310	Brand
MICARDIS	TELMISARTAN TAB 40 MG	36150070000320	Brand
MICARDIS	TELMISARTAN TAB 80 MG	36150070000340	Brand
MICARDIS HCT	TELMISARTAN-HYDROCHLOROTHIAZIDE TAB 40-12.5 MG	36994002600320	Brand
MICARDIS HCT	TELMISARTAN-HYDROCHLOROTHIAZIDE TAB 80-12.5 MG	36994002600340	Brand
MICARDIS HCT	TELMISARTAN-HYDROCHLOROTHIAZIDE TAB 80-25 MG	36994002600345	Brand

MOBIC	MELOXICAM TAB 7.5 MG	66100052000320	Brand
MOBIC	MELOXICAM TAB 15 MG	66100052000330	Brand
NALFON	FENOPROFEN CALCIUM CAP 400 MG	66100010100120	Brand
NALFON	FENOPROFEN CALCIUM TAB 600 MG	66100010100305	Brand
NATROBA	SPINOSAD SUSP 0.9%	90900048001820	Brand
NEURONTIN	GABAPENTIN CAP 100 MG	72600030000110	Brand
NEURONTIN	GABAPENTIN CAP 300 MG	72600030000130	Brand
NEURONTIN	GABAPENTIN CAP 400 MG	72600030000140	Brand
NEURONTIN	GABAPENTIN TAB 600 MG	72600030000330	Brand
NEURONTIN	GABAPENTIN TAB 800 MG	72600030000340	Brand
NEURONTIN	GABAPENTIN ORAL SOLN 250 MG/5ML	72600030002020	Brand
NIASPAN	NIACIN TAB ER 500 MG (ANTIHYPERLIPIDEMIC)	39450050000450	Brand
NIASPAN	NIACIN TAB ER 750 MG (ANTIHYPERLIPIDEMIC)	39450050000460	Brand
NIASPAN	NIACIN TAB ER 1000 MG (ANTIHYPERLIPIDEMIC)	39450050000470	Brand
PAXIL	PAROXETINE HCL TAB 10 MG	58160060000310	Brand
PAXIL	PAROXETINE HCL TAB 20 MG	58160060000320	Brand
PAXIL	PAROXETINE HCL TAB 30 MG	58160060000330	Brand
PAXIL	PAROXETINE HCL TAB 40 MG	58160060000340	Brand
PAXIL CR	PAROXETINE HCL TAB ER 24HR 12.5 MG	58160060007520	Brand
PAXIL CR	PAROXETINE HCL TAB ER 24HR 25 MG	58160060007530	Brand
PAXIL CR	PAROXETINE HCL TAB ER 24HR 37.5 MG	58160060007540	Brand
PLAVIX	CLOPIDOGREL BISULFATE TAB 75 MG (BASE EQUIV)	85158020100320	Brand
PRED FORTE	PREDNISOLONE ACETATE OPHTH SUSP 1%	86300050101815	Brand
ZESTRIL	LISINOPRIL TAB 2.5 MG	36100030000303	Brand
ZESTRIL	LISINOPRIL TAB 5 MG	36100030000305	Brand
ZESTRIL	LISINOPRIL TAB 10 MG	36100030000310	Brand
ZESTRIL	LISINOPRIL TAB 20 MG	36100030000315	Brand
ZESTRIL	LISINOPRIL TAB 30 MG	36100030000324	Brand
ZESTRIL	LISINOPRIL TAB 40 MG	36100030000330	Brand
QUESTRAN	CHOLESTYRAMINE POWDER 4 GM/DOSE	39100010002905	Brand

RANEXA	RANOLAZINE TAB ER 12HR 500 MG	32200040007420	Brand
RANEXA	RANOLAZINE TAB ER 12HR 1000 MG	32200040007430	Brand
RELPAX	ELETRIPTAN HYDROBROMIDE TAB 20 MG (BASE EQUIVALENT)	67406025100320	Brand
RELPAX	ELETRIPTAN HYDROBROMIDE TAB 40 MG (BASE EQUIVALENT)	67406025100340	Brand
RENAGEL	SEVELAMER HCL TAB 800 MG	52800070100340	Brand
RESTORIL	TEMAZEPAM CAP 7.5 MG	60201030000103	Brand
RESTORIL	TEMAZEPAM CAP 15 MG	60201030000105	Brand
RESTORIL	TEMAZEPAM CAP 22.5 MG	60201030000108	Brand
RESTORIL	TEMAZEPAM CAP 30 MG	60201030000110	Brand
RISPERDAL	RISPERIDONE TAB 0.5 MG	59070070000306	Brand
RISPERDAL	RISPERIDONE TAB 1 MG	59070070000310	Brand
RISPERDAL	RISPERIDONE TAB 2 MG	59070070000320	Brand
RISPERDAL	RISPERIDONE TAB 3 MG	59070070000330	Brand
RISPERDAL	RISPERIDONE TAB 4 MG	59070070000340	Brand
RISPERDAL	RISPERIDONE SOLN 1 MG/ML	59070070002010	Brand
SEROQUEL	QUETIAPINE FUMARATE TAB 25 MG	59153070100310	Brand
SEROQUEL	QUETIAPINE FUMARATE TAB 50 MG	59153070100314	Brand
SEROQUEL	QUETIAPINE FUMARATE TAB 100 MG	59153070100320	Brand
SEROQUEL	QUETIAPINE FUMARATE TAB 200 MG	59153070100330	Brand
SEROQUEL	QUETIAPINE FUMARATE TAB 300 MG	59153070100340	Brand
SEROQUEL	QUETIAPINE FUMARATE TAB 400 MG	59153070100350	Brand
SEROQUEL XR	QUETIAPINE FUMARATE TAB ER 24HR 50 MG	59153070107505	Brand
SEROQUEL XR	QUETIAPINE FUMARATE TAB ER 24HR 150 MG	59153070107515	Brand
SEROQUEL XR	QUETIAPINE FUMARATE TAB ER 24HR 200 MG	59153070107520	Brand
SEROQUEL XR	QUETIAPINE FUMARATE TAB ER 24HR 300 MG	59153070107530	Brand
SEROQUEL XR	QUETIAPINE FUMARATE TAB ER 24HR 400 MG	59153070107540	Brand
SILVADENE	SILVER SULFADIAZINE CREAM 1%	90450030003710	Brand
SKELAXIN	METAXALONE TAB 800 MG	75100060000320	Brand
SOMA	CARISOPRODOL TAB 250 MG	75100020000304	Brand

SOMA	CARISOPRODOL TAB 350 MG	75100020000305	Brand
SUBOXONE	BUPRENORPHINE HCL-NALOXONE HCL SL FILM 2-0.5 MG (BASE EQUIV)	65200010208220	Brand
SUBOXONE	BUPRENORPHINE HCL-NALOXONE HCL SL FILM 4-1 MG (BASE EQUIV)	65200010208230	Brand
SUBOXONE	BUPRENORPHINE HCL-NALOXONE HCL SL FILM 8-2 MG (BASE EQUIV)	65200010208240	Brand
SUBOXONE	BUPRENORPHINE HCL-NALOXONE HCL SL FILM 12-3 MG (BASE EQUIV)	65200010208250	Brand
TEGRETOL	CARBAMAZEPINE SUSP 100 MG/5ML	72600020001810	Brand
TEGRETOL	CARBAMAZEPINE TAB 200 MG	72600020000305	Brand
TEGRETOL-XR	CARBAMAZEPINE TAB ER 12HR 100 MG	72600020007410	Brand
TEGRETOL-XR	CARBAMAZEPINE TAB ER 12HR 200 MG	72600020007420	Brand
TEGRETOL-XR	CARBAMAZEPINE TAB ER 12HR 400 MG	72600020007440	Brand
TENORMIN	ATENOLOL TAB 25 MG	33200020000303	Brand
TENORMIN	ATENOLOL TAB 50 MG	33200020000305	Brand
TENORMIN	ATENOLOL TAB 100 MG	33200020000310	Brand
TIKOSYN	DOFETILIDE CAP 125 MCG (0.125 MG)	35400025000110	Brand
TIKOSYN	DOFETILIDE CAP 250 MCG (0.25 MG)	35400025000120	Brand
TIKOSYN	DOFETILIDE CAP 500 MCG (0.5 MG)	35400025000130	Brand
TIMOPTIC	TIMOLOL MALEATE OPHTH SOLN 0.25%	86250030102005	Brand
TIMOPTIC OCUDOSE	TIMOLOL MALEATE PRESERVATIVE FREE OPHTH SOLN 0.25%	86250030102006	Brand
TIMOPTIC	TIMOLOL MALEATE OPHTH SOLN 0.5%	86250030102010	Brand
TIMOPTIC OCUDOSE	TIMOLOL MALEATE PRESERVATIVE FREE OPHTH SOLN 0.5%	86250030102011	Brand
TIMOPTIC-XE	TIMOLOL MALEATE OPHTH GEL FORMING SOLN 0.25%	86250030107620	Brand
TIMOPTIC-XE	TIMOLOL MALEATE OPHTH GEL FORMING SOLN 0.5%	86250030107630	Brand
TOPAMAX	TOPIRAMATE TAB 25 MG	72600075000310	Brand
TOPAMAX	TOPIRAMATE TAB 50 MG	72600075000320	Brand
TOPAMAX	TOPIRAMATE TAB 100 MG	72600075000330	Brand
TOPAMAX	TOPIRAMATE TAB 200 MG	72600075000340	Brand
TOPAMAX SPRINKLE	TOPIRAMATE SPRINKLE CAP 15 MG	72600075006820	Brand
TOPAMAX SPRINKLE	TOPIRAMATE SPRINKLE CAP 25 MG	72600075006830	Brand
TRICOR	FENOFIBRATE TAB 48 MG	39200025000310	Brand

TRICOR	FENOFIBRATE TAB 145 MG	39200025000323	Brand
TRILEPTAL	OXCARBAZEPINE TAB 150 MG	72600046000310	Brand
TRILEPTAL	OXCARBAZEPINE TAB 300 MG	72600046000320	Brand
TRILEPTAL	OXCARBAZEPINE TAB 600 MG	72600046000340	Brand
TRILEPTAL	OXCARBAZEPINE SUSP 300 MG/5ML (60 MG/ML)	72600046001820	Brand
UCERIS	BUDESONIDE TAB ER 24HR 9 MG	22100012007530	Brand
VALTREX	VALACYCLOVIR HCL TAB 500 MG	12405085100310	Brand
VALTREX	VALACYCLOVIR HCL TAB 1 GM	12405085100320	Brand
VECTICAL	CALCITRIOL OINT 3 MCG/GM	90250028004220	Brand
VIGAMOX	MOXIFLOXACIN HCL OPHTH SOLN 0.5% (BASE EQUIV)	86101038102020	Brand
WELCHOL	COLESEVELAM HCL PACKET FOR SUSP 3.75 GM	39100016103040	Brand
WELCHOL	COLESEVELAM HCL TAB 625 MG	39100016100330	Brand
XALATAN	LATANOPROST OPHTH SOLN 0.005%	86330050002020	Brand
ZANAFLEX	TIZANIDINE HCL CAP 2 MG (BASE EQUIVALENT)	75100090100110	Brand
ZANAFLEX	TIZANIDINE HCL CAP 4 MG (BASE EQUIVALENT)	75100090100120	Brand
ZANAFLEX	TIZANIDINE HCL CAP 6 MG (BASE EQUIVALENT)	75100090100130	Brand
ZANAFLEX	TIZANIDINE HCL TAB 4 MG (BASE EQUIVALENT)	75100090100320	Brand
ZONEGRAN	ZONISAMIDE CAP 25 MG	72600090000105	Brand
ZONEGRAN	ZONISAMIDE CAP 100 MG	72600090000120	Brand
ZOVIRAX	ACYCLOVIR CREAM 5%	90350010003720	Brand
ZYPREXA	OLANZAPINE TAB 2.5 MG	59157060000305	Brand
ZYPREXA	OLANZAPINE TAB 5 MG	59157060000310	Brand
ZYPREXA	OLANZAPINE TAB 7.5 MG	59157060000315	Brand
ZYPREXA	OLANZAPINE TAB 10 MG	59157060000320	Brand
ZYPREXA	OLANZAPINE TAB 15 MG	59157060000330	Brand
ZYPREXA	OLANZAPINE TAB 20 MG	59157060000340	Brand
ZYPREXA	OLANZAPINE FOR IM INJ 10 MG	59157060002120	Brand
AVODART	DUTASTERIDE CAP 0.5 MG	56851020000120	Brand
GOLYTELY	PEG 3350-KCL-NA BICARB-NACL-NA SULFATE FOR SOLN 236 GM	46992005302130	Brand

VESICARE	SOLIFENACIN SUCCINATE TAB 5 MG	54100055200320	Brand
VESICARE	SOLIFENACIN SUCCINATE TAB 10 MG	54100055200330	Brand
VANADOM	CARISOPRODOL TAB 350 MG	75100020000305	Brand
AZOPT	BRINZOLAMIDE OPHTH SUSP 1%	86802320001820	Brand
TRAVATAN Z	TRAVOPROST OPHTH SOLN 0.004% (BENZALKONIUM FREE) (BAK FREE)	86330070002025	Brand
BYSTOLIC	NEBIVOLOL HCL TAB 2.5 MG (BASE EQUIVALENT)	33200040100310	Brand
BYSTOLIC	NEBIVOLOL HCL TAB 5 MG (BASE EQUIVALENT)	33200040100320	Brand
BYSTOLIC	NEBIVOLOL HCL TAB 10 MG (BASE EQUIVALENT)	33200040100330	Brand
BYSTOLIC	NEBIVOLOL HCL TAB 20 MG (BASE EQUIVALENT)	33200040100340	Brand
BROVANA	ARFORMOTEROL TARTRATE SOLN NEBU 15 MCG/2ML (BASE EQUIV)	44201012102520	Brand
LATISSE	BIMATOPROST SOLN 0.03%	90734020002020	Brand
NITROSTAT	NITROGLYCERIN SL TAB 0.3MG	32100030000710	Brand
NITROSTAT	NITROGLYCERIN SL TAB 0.4MG	32100030000715	Brand
NITROSTAT	NITROGLYCERIN SL TAB 0.6MG	32100030000720	Brand
TOPICORT	DESOXIMETASONE SPRAY 0.25%	90550040000910	Brand
ARTHROTEC 50	DICLOFENAC W/MISOPROSTOL TAB DELAYED RELEASE 50-0.2MG	66109902200620	Brand
PROPECIA	FINASTERIDE TAB 1MG	90736030000310	Brand
ZOVIRAX	ACYCLOVIR OINT 5%	90350010004205	Brand
HALOG	HALCINONIDE CREAM 0.1%	90550070003710	Brand
DILANTIN-125	PHENYTOIN SUSP 125MG/5ML	72200030001810	Brand
ZOLOFT	SERTRALINE HCL TAB 25 MG	58160070100305	Brand
ZOLOFT	SERTRALINE HCL TAB 50 MG	58160070100310	Brand
ZOLOFT	SERTRALINE HCL TAB 100 MG	58160070100320	Brand
ACZONE	DAPSONE GEL 5%	90051015004020	Brand
VIMPAT	LACOSAMIDE TAB 50 MG	72600036000320	Brand
VIMPAT	LACOSAMIDE TAB 100 MG	72600036000330	Brand
VIMPAT	LACOSAMIDE TAB 150 MG	72600036000340	Brand
VIMPAT	LACOSAMIDE TAB 200 MG	72600036000350	Brand
VIMPAT	LACOSAMIDE IV INJ 200 MG/20ML (10 MG/ML)	72600036002020	Brand

VIMPAT	LACOSAMIDE ORAL SOLUTION 10 MG/ML	72600036002060	Brand
COMBIGAN	BRIMONIDINE TARTRATE-TIMOLOL MALEATE OPHTH SOLN 0.2-0.5%	86259902152020	Brand
ACZONE	DAPSONE GEL 7.5%	90051015004030	Brand
CARDIZEM LA	DILTIAZEM HCL TAB ER 24HR 120 MG	34000010107525	Brand
CARDIZEM LA	DILTIAZEM HCL TAB ER 24HR 180 MG	34000010107530	Brand
CARDIZEM LA	DILTIAZEM HCL TAB ER 24HR 240 MG	34000010107540	Brand
CARDIZEM LA	DILTIAZEM HCL TAB ER 24HR 300 MG	34000010107550	Brand
CARDIZEM LA	DILTIAZEM HCL TAB ER 24HR 360 MG	34000010107560	Brand
CARDIZEM LA	DILTIAZEM HCL TAB ER 24HR 420 MG	34000010107570	Brand
EFFEXOR XR	VENLAFAXINE HCL CAP ER 24HR 37.5 MG (BASE EQUIVALENT)	58180090107020	Brand
EFFEXOR XR	VENLAFAXINE HCL CAP ER 24HR 75 MG (BASE EQUIVALENT)	58180090107030	Brand
EFFEXOR XR	VENLAFAXINE HCL CAP ER 24HR 150 MG (BASE EQUIVALENT)	58180090107050	Brand
ARIMIDEX	ANASTROZOLE TAB 1 MG	21402810000310	Brand
DEPAKOTE	DIVALPROEX SODIUM TAB DELAYED RELEASE 125 MG	72500010100605	Brand
DEPAKOTE	DIVALPROEX SODIUM TAB DELAYED RELEASE 250 MG	72500010100610	Brand
DEPAKOTE	DIVALPROEX SODIUM TAB DELAYED RELEASE 500 MG	72500010100615	Brand
PLAQUENIL	HYDROXYCHLOROQUINE SULFATE TAB 200 MG	13000020100305	Brand
LATUDA	LURASIDONE HCL TAB 20 MG	59400023100310	Brand
LATUDA	LURASIDONE HCL TAB 40 MG	59400023100320	Brand
LATUDA	LURASIDONE HCL TAB 60 MG	59400023100330	Brand
LATUDA	LURASIDONE HCL TAB 80 MG	59400023100340	Brand
LATUDA	LURASIDONE HCL TAB 120 MG	59400023100350	Brand
DELESTROGEN	ESTRADIOL VALERATE IM IN OIL 10 MG/ML	24000035201705	Brand
QUESTRAN	CHOLESTYRAMINE POWDER PACKETS 4 GM	39100010003005	Brand
QUESTRAN LIGHT	CHOLESTYRAMINE LIGHT POWDER 4 GM/DOSE	39100010102905	Brand
PROMETRIUM	PROGESTERONE CAP 100 MG	26000040000120	Brand
PROMETRIUM	PROGESTERONE CAP 200 MG	26000040000140	Brand

PREDNISOLONE ACETATE P-F	PREDNISOLONE ACETATE OPHTH SUSP 1%	86300050101815	Brand
INDERAL LA	PROPRANOLOL HCL CAP ER 24HR 60 MG	33100040107025	Brand
INDERAL LA	PROPRANOLOL HCL CAP ER 24HR 80 MG	33100040107030	Brand
INDERAL LA	PROPRANOLOL HCL CAP ER 24HR 120 MG	33100040107035	Brand
INDERAL LA	PROPRANOLOL HCL CAP ER 24HR 160 MG	33100040107040	Brand
SOVUNA	HYDROXYCHLOROQUINE SULFATE TAB 200 MG	13000020100305	Brand
SOVUNA	HYDROXYCHLOROQUINE SULFATE TAB 300 MG	13000020100308	Brand
ALPHAGAN P	BRIMONIDINE TARTRATE OPHTH SOLN 0.1%	86602020102005	Brand
RISPERDAL CONSTA	RISPERIDONE MICROSPHERES FOR IM EXTENDED REL SUSP 12.5 MG	5907007010G210	Brand
RISPERDAL CONSTA	RISPERIDONE MICROSPHERES FOR IM EXTENDED REL SUSP 25 MG	5907007010G220	Brand
RISPERDAL CONSTA	RISPERIDONE MICROSPHERES FOR IM EXTENDED REL SUSP 37.5 MG	5907007010G230	Brand
RISPERDAL CONSTA	RISPERIDONE MICROSPHERES FOR IM EXTENDED REL SUSP 50 MG	5907007010G240	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 30 day supply, or intolerance to target's generic counterpart

2 . Background

Benefit/Coverage/Program Information

Table of Target Drugs which require trial and failure or intolerance to generic counterpart

ABILIFY	592500150003**
ALPHAGAN P SOLN 0.1%	86602020102005
ALTACE	361000500001**
ARIMIDEX	21402810000310
ARTHROTEC 75 TAB	66109902200630
ATACAND	361500201003**
AVAPRO	361500300003**
AVODART CAP 0.5MG	56851020000120
AZOPT	86802320001820
BYSTOLIC	332000401003**
CANASA SUP 1000MG	52500030005240
CARBATROL	726000200069**
CARDIZEM LA	340000101275**
CARNITOR SOL 1GM/10ML	30903045102010
CARNITOR TAB 330MG	30903045100330
CATAPRES-TTS	362010100088**
CELEXA	581600201003**

CIALIS	403040800003**
CIALIS TAB 2.5MG	40304080000302
CIALIS TAB 5MG	40304080000305
CLARINEX TAB 5MG	41550021000320
CLIMARA	240000350088**
CLOBEX LOT 0.05%	90550025104110
CLOBEX SHA 0.05%	90550025104520
CLOBEX SPR 0.05%	90550025100910
COLESTID	391000201027**
COLESTID	391000201030**
COLESTID TAB 1GM	39100020100320
COREG	333000070003**
COREG CR	333000072070**
CORTEF	221000250003**
COSOPT SOL 22.3-6.8	86259902202020
COSOPT PF SOL	86259902202060
COZAAR	361500402003**

DELESTROGEN INJ	240000352017**
DEPAKOTE ER	725000101075**
DEPAKOTE	725000101006**
DEPAKOTE SPR CAP 125MG	7250001010H120
EFFEXOR XR	581800901070**
EPIDUO GEL 0.1-2.5%	90059902034020
ESTRACE	240000350003**
ESTRACE VAG CRE 0.01%	55350020003705
EXFORGE	369930021003**
FIORICET CAP	64991003100108
FIORICET CAP CODEINE	65991004100113
FLOMAX CAP 0.4MG	56852070100110
GENERESS FE CHW	25990003600540
GOLYTELY	469920053021**
HYZAAR	369940024503**
IMITREX INJ	6740607010D5**
IMITREX INJ	6740607010E2**

IMITREX INJ 6MG/0.5	674060701020**
IMITREX SPRAY	674060700020**
IMITREX TABLET	674060701003**
INDERAL LA CAP	331000401070**
KEPPRA	726000430003**
KEPPRA SOL 100MG/ML	72600043002020
KEPPRA XR	726000430075**
KLONOPIN	721000100003**
KLONOPIN TAB 2MG	72100010000315
K-TAB	797000300004**
LATUDA	5940002310**
LAMICTAL	726000400003**
LAMICTAL	726000400005**
LAMICTAL KIT START 35	72600040006420
LAMICTAL KIT START 49	72600040006430
LAMICTAL KIT START 98	72600040006435
LAMICTAL ODT	726000400072**
LAMICTAL ODT KIT	72600040006450

LAMICTAL ODT KIT	72600040006455
LAMICTAL ODT KIT	72600040006460
LAMICTAL XR	726000400075**
LASIX	372000300003**
LOESTRIN TAB 1/20-21	25990002600310
LOESTRIN 21 TAB 1.5/30	25990002600320
LOESTRIN FE TAB 1.5/30	25990003610320
LOESTRIN FE TAB 1/20	25990003610310
LOTREL	369915022001**
LYRICA	726000570001**
LYRICA CAP 300MG	72600057000160
LYRICA SOL 20MG/ML	72600057002020
MAXALT	674060601003**
MAXALT-MLT	674060601072**
MICARDIS	361500700003**
MICARDIS HCT	369940026003**
MOBIC	661000520003**

NALFON CAP 400MG	66100010100120
NALFON TAB 600MG	66100010100305
NATROBA SUS 0.9%	90900048001820
NEURONTIN	726000300001**
NEURONTIN	726000300003**
NEURONTIN SOL 250/5ML	72600030002020
NIASPAN	394500500004**
PAXIL	581600600003**
PAXIL CR	581600600075**
PLAQUENIL TAB 200MG	13000020100305
PLAVIX	851580201003**
PRED FORTE SUS 1% OP	86300050101815
PREDNISOLONE ACETATE P- F	86300050101815
PROMETRIUM CAP	260000400001**
QUESTRAN	391000100029**
QUESTRAN	391000100030**
RANEXA	322000400074**
RELPAX	674060251003**

RENAGEL	528000701003**
RESTORIL	602010300001**
RISPERDAL TAB	590700700003**
RISPERDAL SOL 1MG/ML	59070070002010
RISPERDAL CONSTA	5907007010G2**
SAFYRAL TAB	25990003200330
SEASONIQUE TAB	25993002300330
SEROQUEL	591530701003**
SEROQUEL TAB 300MG	59153070100340
SEROQUEL TAB 400MG	59153070100350
SEROQUEL XR	591530701075**
SEROQUEL XR TAB 200MG	59153070107520
SILVADENE CRE 1%	90450030003710
SKELAXIN TAB 800MG	75100060000320
SOMA	751000200003**
SUBOXONE MIS 12-3MG	65200010208250
SUBOXONE MIS 2-0.5MG	65200010208220

SUBOXONE MIS 4-1MG	65200010208230
SUBOXONE MIS 8-2MG	65200010208240
TAMIFLU SUS 6MG/ML	12504060201910
TEGRETOL SUS 100/5ML	72600020001810
TEGRETOL TAB 200MG	72600020000305
TEGRETOL-XR	726000200074**
TENORMIN	332000200003**
TIKOSYN	354000250001**
TIMOPTIC SOL 0.25% OP	86250030102005
TIMOPTIC SOL 0.5% OP	86250030102010
TIMOPTIC OCU SOL 0.25% OP	86250030102006
TIMOPTIC OCU SOL 0.5% OP	86250030102011
TIMOPTIC-XE SOL 0.5% OP	86250030107630
TIMOPTIC-XE SOL 0.25% OP	86250030107620
TOPAMAX	726000750003**

TOPAMAX SPR	726000750068**
TRAVATAN Z	86330070002025
TRICOR TAB 145MG	39200025000323
TRICOR TAB 48MG	39200025000310
TRILEPTAL	726000460003**
TRILEPTAL SUS 300MG/5M	72600046001820
UCERIS TAB 9MG	22100012007530
VALTREX	124050851003**
VANADOM	75100020000305
VECTICAL OIN 3MCG/GM	90250028004220
VESICARE	541000552003**
VIGAMOX DRO 0.5%	86101038102020
WELCHOL PAK 3.75GM	39100016103040
WELCHOL TAB 625MG	39100016100330
XALATAN SOL 0.005%	86330050002020
YASMIN 28 TAB 3-0.03MG	25990002150320

ZANAFLEX	751000901001**
ZANAFLEX TAB 4MG	75100090100320
ZESTRIL	361000300003**
ZONEGRAN	726000900001**
ZOVIRAX CRE 5%	90350010003720
ZYPREXA	591570600003**
ZYPREXA INJ 10MG	59157060002120
BROVANA	442010121025**
LATISSE	90734020002020
NITROSTAT	32100030000710
NITROSTAT	32100030000715
NITROSTAT	32100030000720
TOPICORT	90550040000910
ARTHROTEC 50	66109902200620
PROPECIA	90736030000310
ZOVIRAX	90350010004205
HALOG	90550070003710
DILANTIN-125	72200030001810
COMBIGAN	862599021520**
ZOLOFT	581600701003**
ACZONE	90051015004020

ACZONE	90051015004030
VIMPAT	726000360003**
VIMPAT	726000360020**

3 . Revision History

Date	Notes
2/18/2025	Quartz Com/EHB copied to mirrow OptumRx/EHB

Prior Authorization Guideline

Guideline ID	GL-233253
Guideline Name	Gilenya (fingolimod) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	12/14/2022
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Gilenya (fingolimod)
Multiple Sclerosis Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

2 . Criteria

Product Name:Generic fingolimod, Brand Gilenya 0.25mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FINGOLIMOD	FINGOLIMOD HCL CAP 0.5 MG (BASE EQUIV)	62407025100120	
GILENYA	FINGOLIMOD HCL CAP 0.25 MG (BASE EQUIV)	62407025100110	

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Patient is 10 years of age or older

AND

3 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Brand Gilenya 0.5mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GILENYA	FINGOLIMOD HCL CAP 0.5 MG (BASE EQUIV)	62407025100120	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Patient is 10 years of age or older

AND

3 - Failure after a trial of at least 4 weeks, or intolerance to generic fingolimod

AND

4 - One of the following:

4.1 Patient is less than 18 years of age

OR

4.2 Both of the following:

4.2.1 Patient is 18 years of age or older

AND

4.2.2 One of the following:

4.2.2.1 Failure after a trial of at least 4 weeks, contraindication or intolerance to two disease-modifying therapies from the following:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod

- Kesimpta (ofatumumab)
- Mayzent (siponimod)
- Vumerity (diroximel fumarate)
- Zeposia (ozanimod)

OR

4.2.2.2 Both of the following:

- For continuation of prior therapy, defined as no more than a 45-day gap in therapy
- Patient demonstrates positive clinical response to therapy

AND

5 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Brand Gilenya, generic fingolimod	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GILENYA	FINGOLIMOD HCL CAP 0.25 MG (BASE EQUIV)	62407025100110	Brand
GILENYA	FINGOLIMOD HCL CAP 0.5 MG (BASE EQUIV)	62407025100120	Brand
FINGOLIMOD	FINGOLIMOD HCL CAP 0.5 MG (BASE EQUIV)	62407025100120	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Failure after a trial of at least 4 weeks, or intolerance to generic fingolimod (applies to Brand Gilenya 0.5mg only)

AND

3 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Brand Gilenya 0.5mg	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GILENYA	FINGOLIMOD HCL CAP 0.5 MG (BASE EQUIV)	62407025100120	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Patient is 10 years of age or older

AND

3 - Both of the following:

3.1 Submission of medical records (e.g., chart notes) confirming lack of adequate clinical response (with related symptoms) with generic fingolimod

AND

3.2 Submission of medical records confirming generic fingolimod has not been effective AND valid clinical justification provided explaining how Brand Gilenya 0.5mg is expected to provide benefit when generic fingolimod has not been shown to be effective despite having the same active ingredient

AND

4 - One of the following:

4.1 Patient is less than 18 years of age

OR

4.2 Both of the following:

4.2.1 Patient is 18 years of age or older

AND

4.2.2 One of the following:

4.2.2.1 Submission of medical records (e.g., chart notes) or paid claims confirming failure after a trial of at least 4 weeks, contraindication or intolerance to two disease-modifying therapies from the following:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Kesimpta (ofatumumab)
- Mayzent (siponimod)

- Vumerity (diroximel fumarate)
- Zeposia (ozanimod)

OR

4.2.2.2 Both of the following:

4.2.2.2.1 Submission of medical records (e.g., chart notes) or paid claims confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

4.2.2.2.2 Patient demonstrates positive clinical response to therapy

AND

5 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

6 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. According to the National MS Society, of the four disease courses that have been identified in MS, relapsing-remitting MS (RRMS) is characterized primarily by relapses, and secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. These two constitute “relapsing forms of MS” if they describe a disease course that is characterized by the occurrence of relapses. [3] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [2]
B. Initiation of treatment with an interferon beta medication or glatiramer acetate should be considered as soon as possible following a definite diagnosis of MS with active, relapsing disease, and may also be considered for selected patients with a first attack who are at high risk of MS. [2]
C. Based on several years of experience with glatiramer acetate and interferon beta 1a and 1b, it is the consensus of researchers and clinicians with expertise in MS that these agents are likely to reduce future disease activity and improve quality of life for many

individuals with relapsing forms of MS, including those with secondary progressive disease who continue to have relapses. For those who are appropriate candidates for one of these drugs, treatment must be sustained for years. Cessation of treatment may result in a resumption of pre-treatment disease activity. [2]

D. MS specialists will use Copaxone in relapsing forms of disease, including SPMS with relapses. While there have been no trials of Copaxone in SPMS (so we have no evidenced-based data upon which to make decisions or recommendations), it's clear that where there are relapses, the injectable therapies are partially effective – they reduce relapses and new lesions on MRI. In SPMS, the trials suggest that the interferons work better in earlier, more inflammatory (i.e. those with relapses prior to the trial and with gadolinium-enhancing lesions, which is the MRI equivalent of active inflammation). Since Copaxone and the interferons appear to have rather similar efficacy in the head-to-head trials, most assume that Copaxone has a similar efficacy in SPMS: where there are relapses or active inflammation on MRI, it will likely have some benefit. Thus, most MS specialists will use Copaxone in patients with SPMS who have persistent relapses. [4]
E. The advantage of using combination disease-modifying therapy (DMT) compared to monotherapy DMT use has not been demonstrated, but there are safety concerns, such as reduced efficacy or disease aggravation, with combination use. [5, 6]

4 . References

1. Gilenya Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2023.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.
3. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed March 29, 2019.
4. Per clinical consultation with MS specialist, December 29, 2010.
5. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. Mayo Clinic Proceedings, 89(2), 225-240.
6. Sorensen, P., Lycke, J., Erälinna, J., Edland, A., Wu, X., & Frederiksen, J. et al. (2011). Simvastatin as add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (SIMCOMBIN study): a placebo-controlled randomised phase 4 trial. The Lancet Neurology, 10(8), 691-701.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Gilotrif (afatinib)

Prior Authorization Guideline

Guideline ID	GL-229097
Guideline Name	Gilotrif (afatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/8/2013
P&T Revision Date:	11/21/2025

1 . Indications

Drug Name: Gilotrif (afatinib)
EGFR Mutation-Positive, Metastatic Non-Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. Limitation of Use: Safety and efficacy of Gilotrif have not been established in patients whose tumors have resistant EGFR mutations. **Previously Treated, Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)** Indicated for the treatment of patients with metastatic, squamous non-small cell lung cancer (NSCLC) progressing after platinum-based chemotherapy.

2 . Criteria

Product Name:Gilotrif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GILOTRIF	AFATINIB DIMALEATE TAB 20 MG (BASE EQUIVALENT)	21360006100320	Brand
GILOTRIF	AFATINIB DIMALEATE TAB 30 MG (BASE EQUIVALENT)	21360006100330	Brand
GILOTRIF	AFATINIB DIMALEATE TAB 40 MG (BASE EQUIVALENT)	21360006100340	Brand

Approval Criteria

1 - Diagnosis of advanced or metastatic (stage IIIB or IV) non-small cell lung cancer (NSCLC)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Presence of non-resistant epidermal growth factor (EGFR) mutations as detected by an U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AND

2.1.2 Gilotrif will be used as first-line treatment

OR

2.2 Both of the following:

2.2.1 Diagnosis of squamous NSCLC

AND

2.2.2 Disease progressed after platinum-based chemotherapy (e.g., cisplatin, carboplatin)

Product Name:Gilotrif	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GILOTRIF	AFATINIB DIMALEATE TAB 20 MG (BASE EQUIVALENT)	21360006100320	Brand
GILOTRIF	AFATINIB DIMALEATE TAB 30 MG (BASE EQUIVALENT)	21360006100330	Brand
GILOTRIF	AFATINIB DIMALEATE TAB 40 MG (BASE EQUIVALENT)	21360006100340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Gilotrif Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. April 2022.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228863
Guideline Name	Gleevec (imatinib mesylate) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Gleevec (imatinib mesylate)
Chronic myelogenous/myeloid leukemia (CML) Indicated for the treatment of newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase. Gleevec is also indicated for the treatment of patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy. **Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)** Indicated for the treatment of adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Gleevec is also indicated for the treatment of pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy. **Myelodysplastic/myeloproliferative diseases (MDS/MPD)** Indicated for the treatment of adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. **Aggressive systemic mastocytosis (ASM)** Indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit

mutational status unknown.

Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) Indicated for the treatment of adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRa fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRa fusion kinase negative or unknown.

Dermatofibrosarcoma protuberans (DFSP) Indicated for the treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).

Gastrointestinal stromal tumors (GIST) Indicated for the treatment of patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). Gleevec is also indicated for the adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive GIST.

2 . Criteria

Product Name:Brand Gleevec	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name:Brand Gleevec	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name:Generic imatinib	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)

Product Name:Brand Gleevec	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name:Brand Gleevec	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name:Generic imatinib	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL)

Product Name:Brand Gleevec	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name:Brand Gleevec	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name:Generic imatinib	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

Product Name:Brand Gleevec	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name:Brand Gleevec	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name:Generic imatinib	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

Product Name:Brand Gleevec	
Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of at least one of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name:Brand Gleevec

Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of at least one of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name:Generic imatinib	
Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

1 - Diagnosis of at least one of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

Product Name:Brand Gleevec	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of unresectable, recurrent, or metastatic dermatofibrosarcoma protuberans (DFSP)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name:Brand Gleevec	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of unresectable, recurrent, or metastatic dermatofibrosarcoma protuberans (DFSP)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name:Generic imatinib	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

1 - Diagnosis of unresectable, recurrent, or metastatic dermatofibrosarcoma protuberans (DFSP)

Product Name:Brand Gleevec

Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name:Brand Gleevec	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name:Generic imatinib	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

Product Name:Brand Gleevec, Generic imatinib	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Gleevec Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. March 2024

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228434
Guideline Name	Glycopyrrolate Oral Solution
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cuvposa (Glycopyrrolate oral solution)
Chronic Severe Drooling (Sialorrhea) Indicated to reduce chronic severe drooling in patients aged 3 to 16 years with neurologic conditions associated with problem drooling (e.g., cerebral palsy).

2 . Criteria

Product Name:Brand Cuvposa, Generic glycopyrrolate oral solution	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLYCOPYRROLATE	GLYCOPYRROLATE ORAL SOLN 1 MG/5ML	49102030002060	Generic
CUVPOSA	GLYCOPYRROLATE ORAL SOLN 1 MG/5ML	49102030002060	Brand

Approval Criteria

1 - Diagnosis of chronic severe drooling (sialorrhea)

AND

2 - Diagnosis of a neurologic condition (e.g., cerebral palsy) associated with chronic severe drooling (sialorrhea)

AND

3 - Patient is between 3 and 16 years of age

AND

4 - One of the following:

4.1 Trial and failure, or intolerance to generic glycopyrrolate tablets [A]

OR

4.2 Patient requires liquid formulation due to dosing or inability to take tablet formulation

Product Name:Brand Cuvposa, Generic glycopyrrolate oral solution	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

GLYCOPYRROLATE	GLYCOPYRROLATE ORAL SOLN 1 MG/5ML	49102030002060	Generic
CUVPOSA	GLYCOPYRROLATE ORAL SOLN 1 MG/5ML	49102030002060	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in drooling severity compared to baseline)

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to generic glycopyrrolate tablets [A]

OR

2.2 Patient requires liquid formulation due to dosing or inability to take tablet formulation

3 . Endnotes

A. Prior to the approval of glycopyrrolate oral solution, glycopyrrolate tablets were frequently and extensively used off-label in children to treat chronic drooling due to neurological conditions. [2, 3]

4 . References

1. Glycopyrrolate Oral Solution Prescribing Information. Northstar Rx LLC. Memphis, TN. October 2023.
2. Evatt ML. Oral glycopyrrolate for the treatment of chronic severe drooling caused by neurological disorders in children. Neuropsychiatr Dis Treat. 2011;7:543–7.
3. Cuvposa/Glycopyrrolate Center for Drug Evaluation and Research Summary Review. Food and Drug Administration Web site. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022571Orig1s000SumR.pdf. Accessed March 22, 2024.
4. Cuvposa Prescribing Information. Merz Pharmaceuticals, LLC. Raleigh, NC. January 2023.

Prior Authorization Guideline

Guideline ID	GL-228653
Guideline Name	Glycopyrrolate Tablets - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Dartisla ODT (glycopyrrolate), Robinul/Robinul Forte (glycopyrrolate tablet)
Peptic Ulcer, Adjunct Indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. Limitations of Use: Dartisla ODT/Robinul/Robinul Forte are not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established.
Drug Name: Glycate (glycopyrrolate tablet)
Peptic Ulcer, Adjunct Indicated for use as adjunctive therapy in the treatment of peptic ulcer.

2 . Criteria

Product Name:Dartisla ODT, Brand Glycate, Brand Glycopyrrolate tablet, Robinul, Robinul Forte	
Approval Length	3 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARTISLA ODT	GLYCOPYRROLATE TAB DISINTEGRATING 1.7 MG	49102030007220	Brand
ROBINUL	GLYCOPYRROLATE TAB 1 MG	49102030000310	Brand
ROBINUL FORTE	GLYCOPYRROLATE TAB 2 MG	49102030000315	Brand
GLYCATE	GLYCOPYRROLATE TAB 1.5 MG	49102030000312	Generic
GLYCOPYRROLATE	GLYCOPYRROLATE TAB 1.5 MG	49102030000312	Generic

Approval Criteria

1 - Diagnosis of peptic ulcer as confirmed by endoscopy

AND

2 - One of the following: [2]

2.1 Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole)

OR

2.2 Both of the following:

2.2.1 Patient has a contraindication or intolerance to PPIs

AND

2.2.2 Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine)

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to generic glycopyrrolate tablets

OR

3.2 Patient is unable to swallow tablets (Applies to Dartisla ODT only)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Dartisla ODT, Brand Glycate, Brand Glycopyrrolate tablet, Robinul, Robinul Forte	
Approval Length	3 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARTISLA ODT	GLYCOPYRROLATE TAB DISINTEGRATING 1.7 MG	49102030007220	Brand
ROBINUL	GLYCOPYRROLATE TAB 1 MG	49102030000310	Brand
ROBINUL FORTE	GLYCOPYRROLATE TAB 2 MG	49102030000315	Brand
GLYCATE	GLYCOPYRROLATE TAB 1.5 MG	49102030000312	Generic
GLYCOPYRROLATE	GLYCOPYRROLATE TAB 1.5 MG	49102030000312	Generic

Approval Criteria

1 - One of the following:

1.1 Patient's peptic ulcer has not healed as confirmed by endoscopy

OR

1.2 Patient has a new peptic ulcer as confirmed by endoscopy

AND

2 - One of the following: [2-3]

2.1 Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole)

OR

2.2 Both of the following:

2.2.1 Patient has a contraindication or intolerance to PPIs

AND

2.2.2 Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine)

AND

3 - Patient experienced a reduction in peptic ulcer symptoms while on therapy

AND

4 - Other correctable factors (e.g., medication noncompliance, NSAID use, H. pylori infection, etc.) have been addressed

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name:Dartisla ODT	
Approval Length	3 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DARTISLA ODT	GLYCOPYRROLATE TAB DISINTEGRATING 1.7 MG	49102030007220	Brand

Approval Criteria

1 - Diagnosis of peptic ulcer as confirmed by endoscopy

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [2]

2.1 Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole)

OR

2.2 Both of the following:

2.2.1 Patient has a contraindication or intolerance to PPIs

AND

2.2.2 Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Trial and failure, or intolerance to generic glycopyrrolate tablets

OR

3.2 Patient is unable to swallow tablets

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Dartisla ODT	
Approval Length	3 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DARTISLA ODT	GLYCOPYRROLATE TAB DISINTEGRATING 1.7 MG	49102030007220	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming one of the following:

1.1 Patient's peptic ulcer has not healed as confirmed by endoscopy

OR

1.2 Patient has a new peptic ulcer as confirmed by endoscopy

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [2-3]

2.1 Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole)

OR

2.2 Both of the following:

2.2.1 Patient has a contraindication or intolerance to PPIs

AND

2.2.2 Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine)

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has experienced a reduction in peptic ulcer symptoms while on therapy

AND

4 - Submission of medical records (e.g., chart notes) confirming that other correctable factors (e.g., medication noncompliance, NSAID use, H. pylori infection, etc.) have been addressed

AND

5 - Prescribed by or in consultation with a gastroenterologist

3 . Endnotes

A. Leading organizations and guidelines for peptic ulcer disease do not recommend glycopyrrolate as an option for the management of peptic ulcer. Due to the limited data

available, Dartisla ODT treatment duration is based on current treatment guidance with antisecretory therapy which recommends initial treatment with a PPI for a maximum of 12 weeks, and an additional maximum 12 weeks for refractory ulcers, after which surgery should be considered. [2-3]

4 . References

1. Dartisla ODT Prescribing Information. Edenbridge Pharmaceuticals, LLC. Parsippany, NJ. October 2023.
2. Vakil NB. Peptic ulcer disease: Treatment and secondary prevention. UpToDate. Available by subscription at: http://www.uptodate.com/. Accessed February 26, 2024.
3. Vakil NB. Approach to refractory peptic ulcer disease. UpToDate. Available by subscription at: http://www.uptodate.com/. Accessed February 26, 2024.
4. Robinul/Robinul Forte Prescribing Information. Casper Pharma, LLC. East Brunswick, NJ. October 2022.
5. Glycate Prescribing Information. Intra-Sana Laboratories LLC. Las Vegas, NV. August 2021.

Prior Authorization Guideline

Guideline ID	GL-233311
Guideline Name	Gonadotropin-Releasing Hormone Agonists
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	12/12/2005
P&T Revision Date:	8/15/2024

1 . Indications

Drug Name: Lupron Depot (leuprolide acetate) 1-Month 7.5 mg, Lupron Depot 3-Month 22.5 mg, Lupron Depot 4-Month 30 mg, Lupron Depot 6-Month 45 mg
Prostate Cancer Indicated for the treatment of advanced prostate cancer. **Off Label Uses: Gender Dysphoria [16, 17]** Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]
Drug Name: Lupron Depot 1-Month 3.75 mg, Lupron Depot 3-Month 11.25 mg

Endometriosis Indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions. In combination with a norethindrone acetate, it is also indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. Use of norethindrone acetate in combination with LUPRON DEPOT is referred to as add-back therapy, and is intended to reduce the loss of bone mineral density (BMD) and reduce vasomotor symptoms associated with use of LUPRON DEPOT. Limitations of Use: The total duration of therapy with LUPRON DEPOT plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

Uterine Leiomyomata (Fibroids) Indicated for concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. Consider a one-month trial period on iron alone, as some women will respond to iron alone. LUPRON DEPOT may be added if the response to iron alone is considered inadequate. Limitations of Use: Not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

Off Label Uses: Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Leuprolide Acetate

Prostate Cancer Indicated for the palliative treatment of advanced prostatic cancer.

Off Label Uses: Infertility Used for controlled ovarian hyperstimulation to enhance the in vitro fertilization-embryo transfer (IVF-ET) procedure. [5]

Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Leuprolide Acetate Depot, Eligard (leuprolide acetate), Trelstar (triptorelin pamoate)

Prostate Cancer Indicated for the treatment of advanced prostate cancer.

Off Label Uses: Gender Dysphoria [16, 17] Suppression of pubertal development and

gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Lupron Depot-PED (leuprolide acetate)

Central Precocious Puberty (CPP) Indicated for the treatment of pediatric patients with central precocious puberty (CPP).

Off Label Uses: Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Camcevi (leuprolide)

Prostate Cancer Indicated for the treatment of adult patients with advanced prostate cancer.

Drug Name: Supprelin LA (histrelin acetate)

Central Precocious Puberty (CPP) Indicated for the treatment of children with CPP. Children with CPP (neurogenic or idiopathic) have an early onset of secondary sexual characteristics (earlier than 8 years of age in females and 9 years of age in males). They also show a significantly advanced bone age that can result in diminished adult height attainment. Prior to initiation of treatment a clinical diagnosis of CPP should be confirmed by measurement of blood concentrations of total sex steroids, luteinizing hormone (LH) and follicle stimulating hormone (FSH) following stimulation with a GnRH analog, and assessment of bone age versus chronological age. Baseline evaluations should include height and weight measurements, diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), and adrenal steroids to exclude congenital adrenal hyperplasia.

Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Triptodur (triptorelin), Fensolvi (leuprolide acetate)
Central Precocious Puberty (CPP) Indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP). **Gender Dysphoria [16, 17]** Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

2 . Criteria

Product Name:Camcevi, Lupron Depot (7.5 mg, 22.5 mg, 30 mg and 45 mg)	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CAMCEVI	LEUPROLIDE MESYLATE (6 MONTH) EMULSION PREFILLED SYR 42 MG	2140501055E420	Brand
LUPRON DEPOT (1-MONTH)	LEUPROLIDE ACETATE FOR INJ KIT 7.5 MG	21405010106410	Brand
LUPRON DEPOT (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ KIT 22.5 MG	21405010156430	Brand
LUPRON DEPOT (4-MONTH)	LEUPROLIDE ACETATE (4 MONTH) FOR INJ KIT 30 MG	21405010206430	Brand
LUPRON DEPOT (6-MONTH)	LEUPROLIDE ACETATE (6 MONTH) FOR INJ KIT 45 MG	21405010256450	Brand

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer

Product Name:Eligard, Brand Leuprolide Acetate (22.5 mg), Generic leuprolide acetate, Trelstar	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ELIGARD	LEUPROLIDE ACETATE FOR SUBCUTANEOUS INJ KIT 7.5 MG	21405010106415	Brand
ELIGARD	LEUPROLIDE ACETATE (3 MONTH) FOR SUBCUTANEOUS INJ KIT 22.5MG	21405010156432	Brand
ELIGARD	LEUPROLIDE ACETATE (4 MONTH) FOR SUBCUTANEOUS INJ KIT 30 MG	21405010206435	Brand
ELIGARD	LEUPROLIDE ACETATE (6 MONTH) FOR SUBCUTANEOUS INJ KIT 45 MG	21405010256445	Brand
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE INJ KIT 5 MG/ML	21405010106407	Generic
TRELSTAR MIXJECT	TRIPTORELIN PAMOATE FOR IM SUSP 3.75 MG	21405050201920	Brand
TRELSTAR MIXJECT	TRIPTORELIN PAMOATE FOR IM SUSP 11.25 MG	21405050201930	Brand
TRELSTAR MIXJECT	TRIPTORELIN PAMOATE FOR IM SUSP 22.5 MG	21405050201940	Brand
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE (3 MONTH) FOR INJ 22.5 MG	21405010152230	Brand

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer

AND

2 - Trial and failure, contraindication, or intolerance to any brand Lupron formulation

Product Name:Camcevi, Eligard, Brand Leuprolide Acetate (22.5 mg), Generic leuprolide acetate, Lupron Depot (7.5 mg, 22.5 mg, 30 mg and 45 mg), Trelstar	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ELIGARD	LEUPROLIDE ACETATE FOR SUBCUTANEOUS INJ KIT 7.5 MG	21405010106415	Brand
ELIGARD	LEUPROLIDE ACETATE (3 MONTH) FOR SUBCUTANEOUS INJ KIT 22.5MG	21405010156432	Brand
ELIGARD	LEUPROLIDE ACETATE (4 MONTH) FOR SUBCUTANEOUS INJ KIT 30 MG	21405010206435	Brand
ELIGARD	LEUPROLIDE ACETATE (6 MONTH) FOR SUBCUTANEOUS INJ KIT 45 MG	21405010256445	Brand
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE INJ KIT 5 MG/ML	21405010106407	Generic
TRELSTAR MIXJECT	TRIPTORELIN PAMOATE FOR IM SUSP 3.75 MG	21405050201920	Brand
TRELSTAR MIXJECT	TRIPTORELIN PAMOATE FOR IM SUSP 11.25 MG	21405050201930	Brand
TRELSTAR MIXJECT	TRIPTORELIN PAMOATE FOR IM SUSP 22.5 MG	21405050201940	Brand
CAMCEVI	LEUPROLIDE MESYLATE (6 MONTH) EMULSION PREFILLED SYR 42 MG	2140501055E420	Brand
LUPRON DEPOT (1-MONTH)	LEUPROLIDE ACETATE FOR INJ KIT 7.5 MG	21405010106410	Brand
LUPRON DEPOT (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ KIT 22.5 MG	21405010156430	Brand
LUPRON DEPOT (4-MONTH)	LEUPROLIDE ACETATE (4 MONTH) FOR INJ KIT 30 MG	21405010206430	Brand
LUPRON DEPOT (6-MONTH)	LEUPROLIDE ACETATE (6 MONTH) FOR INJ KIT 45 MG	21405010256450	Brand
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE (3 MONTH) FOR INJ 22.5 MG	21405010152230	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUPRON DEPOT (1-MONTH)	LEUPROLIDE ACETATE FOR INJ KIT 3.75 MG	21405010106405	Brand
LUPRON DEPOT (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ KIT 11.25 MG	21405010156420	Brand

Approval Criteria

1 - Diagnosis of endometriosis

AND

2 - One of the following: [8, 12]

2.1 History of inadequate pain control response following a trial of at least 6 months, or history of intolerance or contraindication to one of the following:

- Danazol
- Combination (estrogen/progestin) oral contraceptive
- Progestins

OR

2.2 Patient has had surgical ablation to prevent recurrence

Product Name:Lupron Depot (3.75 mg and 11.25 mg)

Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUPRON DEPOT (1-MONTH)	LEUPROLIDE ACETATE FOR INJ KIT 3.75 MG	21405010106405	Brand
LUPRON DEPOT (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ KIT 11.25 MG	21405010156420	Brand

Approval Criteria

1 - Recurrence of symptoms following a trial of at least 6 months with leuprolide acetate

AND

2 - Used in combination with one of the following:

- Norethindrone 5 mg daily
- Other "add-back" sex-hormones (e.g., estrogen, medroxyprogesterone)
- Other bone-sparing agents (e.g., bisphosphonates such as alendronate, risedronate)

Product Name:Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Uterine Leiomyomata (Fibroids) - For the reduction of the size of fibroids [off-label]
Approval Length	4 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUPRON DEPOT (1-MONTH)	LEUPROLIDE ACETATE FOR INJ KIT 3.75 MG	21405010106405	Brand

LUPRON DEPOT (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ KIT 11.25 MG	21405010156420	Brand

Approval Criteria

1 - For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy) [5]

Product Name:Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Uterine Leiomyomata (Fibroids) - Anemia [4,6]
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUPRON DEPOT (1-MONTH)	LEUPROLIDE ACETATE FOR INJ KIT 3.75 MG	21405010106405	Brand
LUPRON DEPOT (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ KIT 11.25 MG	21405010156420	Brand

Approval Criteria

1 - For the treatment of anemia

AND

2 - Anemia is caused by uterine leiomyomata (fibroids)

AND

3 - Patient has tried and had an inadequate response to at least 1 month of monotherapy with iron

AND

4 - Used in combination with iron therapy

AND

5 - For use prior to surgery

Product Name:Fensolvi, Lupron Depot-PED, Supprelin LA, Triptodur	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUPPRELIN LA	HISTRELIN ACETATE (CPP) IMPLANT KIT 50 MG	30080045106450	Brand
TRIPTODUR	TRIPTORELIN PAMOATE FOR IM ER SUSP 22.5 MG (BASE EQUIV)	3008007040G240	Brand
FENSOLVI	LEUPROLIDE ACET (6 MONTH) FOR INJ PEDIATRIC KIT 45 MG	30080050256450	Brand
LUPRON DEPOT-PED (1-MONTH)	LEUPROLIDE ACETATE FOR INJ PEDIATRIC KIT 7.5 MG	30080050106420	Brand
LUPRON DEPOT-PED (1-MONTH)	LEUPROLIDE ACETATE FOR INJ PEDIATRIC KIT 11.25 MG	30080050106430	Brand
LUPRON DEPOT-PED (1-MONTH)	LEUPROLIDE ACETATE FOR INJ PEDIATRIC KIT 15 MG	30080050106440	Brand
LUPRON DEPOT-PED (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ PEDIATRIC KIT 11.25 MG	30080050156420	Brand
LUPRON DEPOT-	LEUPROLIDE ACETATE (3 MONTH) FOR INJ PEDIATRIC KIT 30 MG	30080050156440	Brand

PED (3-MONTH)			
LUPRON DEPOT-PED	LEUPROLIDE ACET (6 MONTH) FOR IM INJ PEDIATRIC KIT 45 MG	30080050256460	Brand

Approval Criteria

1 - Diagnosis of central precocious puberty (idiopathic or neurogenic)

AND

2 - Early onset of secondary sexual characteristics in one of the following:

- Females less than 8 years of age
- Males less than 9 years of age

AND

3 - Advanced bone age of at least one year compared with chronological age

AND

4 - One of the following:

4.1 Both of the following:

- Patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing
- Peak luteinizing hormone (LH) level above pre-pubertal range

OR

4.2 Patient has a random LH level in the pubertal range

AND

5 - One of the following:

5.1 Patient had one of the following diagnostic evaluations to rule out tumors, when suspected:

- Diagnostic imaging of the brain (MRI or CT scan) (in patients with symptoms suggestive of a brain tumor or in those 6 years of age or younger)
- Pelvic/testicular/adrenal ultrasound (if steroid levels suggest suspicion)
- Adrenal steroids to rule out congenital adrenal hyperplasia (when pubarche precedes thelarche or gonadarche)

OR

5.2 Patient has no suspected tumors

AND

6 - Prescribed by or in consultation with an endocrinologist

Product Name:Fensolvi, Lupron Depot-PED, Supprelin LA, Triptodur	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUPPRELIN LA	HISTRELIN ACETATE (CPP) IMPLANT KIT 50 MG	30080045106450	Brand
TRIPTODUR	TRIPTORELIN PAMOATE FOR IM ER SUSP 22.5 MG (BASE EQUIV)	3008007040G240	Brand
FENSOLVI	LEUPROLIDE ACET (6 MONTH) FOR INJ PEDIATRIC KIT 45 MG	30080050256450	Brand
LUPRON DEPOT-PED (1-MONTH)	LEUPROLIDE ACETATE FOR INJ PEDIATRIC KIT 7.5 MG	30080050106420	Brand
LUPRON DEPOT-	LEUPROLIDE ACETATE FOR INJ PEDIATRIC KIT 11.25 MG	30080050106430	Brand

PED (1-MONTH)			
LUPRON DEPOT-PED (1-MONTH)	LEUPROLIDE ACETATE FOR INJ PEDIATRIC KIT 15 MG	30080050106440	Brand
LUPRON DEPOT-PED (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ PEDIATRIC KIT 11.25 MG	30080050156420	Brand
LUPRON DEPOT-PED (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ PEDIATRIC KIT 30 MG	30080050156440	Brand
LUPRON DEPOT-PED	LEUPROLIDE ACET (6 MONTH) FOR IM INJ PEDIATRIC KIT 45 MG	30080050256460	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, a decrease in the ratio of bone age to chronological age, improvement in final height prediction, LH levels have been suppressed to pre-pubertal levels) [22]

AND

2 - Patient is currently younger than the appropriate time point for the onset of puberty (e.g., females younger than 11 years of age, males younger than 12 years of age) [22]

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name:Generic leuprolide acetate*	
Diagnosis	Treatment of Infertility (off-label) [5]
Approval Length	2 Month [A] (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE INJ KIT 5 MG/ML	21405010106407	Generic

Approval Criteria

1 - Diagnosis of infertility

AND

2 - Used as part of an assisted reproductive technology (ART) protocol

Notes	*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity.

Product Name:Lupron Depot, Lupron Depot-PED, Brand Leuprolide Acetate (22.5 mg), Generic leuprolide acetate, Eligard, Supprelin LA, Trelstar, Triptodur, Camcevi, Fensolvi	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [16, 17]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ELIGARD	LEUPROLIDE ACETATE FOR SUBCUTANEOUS INJ KIT 7.5 MG	21405010106415	Brand
ELIGARD	LEUPROLIDE ACETATE (3 MONTH) FOR SUBCUTANEOUS INJ KIT 22.5MG	21405010156432	Brand
ELIGARD	LEUPROLIDE ACETATE (4 MONTH) FOR SUBCUTANEOUS INJ KIT 30 MG	21405010206435	Brand
ELIGARD	LEUPROLIDE ACETATE (6 MONTH) FOR SUBCUTANEOUS INJ KIT 45 MG	21405010256445	Brand
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE INJ KIT 5 MG/ML	21405010106407	Generic
SUPPRELIN LA	HISTRELIN ACETATE (CPP) IMPLANT KIT 50 MG	30080045106450	Brand
TRELSTAR MIXJECT	TRIPTORELIN PAMOATE FOR IM SUSP 3.75 MG	21405050201920	Brand
TRELSTAR MIXJECT	TRIPTORELIN PAMOATE FOR IM SUSP 11.25 MG	21405050201930	Brand

TRELSTAR MIXJECT	TRIPTORELIN PAMOATE FOR IM SUSP 22.5 MG	21405050201940	Brand
TRIPTODUR	TRIPTORELIN PAMOATE FOR IM ER SUSP 22.5 MG (BASE EQUIV)	3008007040G240	Brand
FENSOLVI	LEUPROLIDE ACET (6 MONTH) FOR INJ PEDIATRIC KIT 45 MG	30080050256450	Brand
CAMCEVI	LEUPROLIDE MESYLATE (6 MONTH) EMULSION PREFILLED SYR 42 MG	2140501055E420	Brand
LUPRON DEPOT (1-MONTH)	LEUPROLIDE ACETATE FOR INJ KIT 3.75 MG	21405010106405	Brand
LUPRON DEPOT (1-MONTH)	LEUPROLIDE ACETATE FOR INJ KIT 7.5 MG	21405010106410	Brand
LUPRON DEPOT (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ KIT 11.25 MG	21405010156420	Brand
LUPRON DEPOT (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ KIT 22.5 MG	21405010156430	Brand
LUPRON DEPOT (4-MONTH)	LEUPROLIDE ACETATE (4 MONTH) FOR INJ KIT 30 MG	21405010206430	Brand
LUPRON DEPOT (6-MONTH)	LEUPROLIDE ACETATE (6 MONTH) FOR INJ KIT 45 MG	21405010256450	Brand
LUPRON DEPOT-PED (1-MONTH)	LEUPROLIDE ACETATE FOR INJ PEDIATRIC KIT 7.5 MG	30080050106420	Brand
LUPRON DEPOT-PED (1-MONTH)	LEUPROLIDE ACETATE FOR INJ PEDIATRIC KIT 11.25 MG	30080050106430	Brand
LUPRON DEPOT-PED (1-MONTH)	LEUPROLIDE ACETATE FOR INJ PEDIATRIC KIT 15 MG	30080050106440	Brand
LUPRON DEPOT-PED (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ PEDIATRIC KIT 11.25 MG	30080050156420	Brand
LUPRON DEPOT-PED (3-MONTH)	LEUPROLIDE ACETATE (3 MONTH) FOR INJ PEDIATRIC KIT 30 MG	30080050156440	Brand
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE (3 MONTH) FOR INJ 22.5 MG	21405010152230	Brand
LUPRON DEPOT-PED	LEUPROLIDE ACET (6 MONTH) FOR IM INJ PEDIATRIC KIT 45 MG	30080050256460	Brand

Approval Criteria

1 - Using gonadotropin for suppression of puberty [16,17]

AND

2 - Diagnosis of gender dysphoria/gender incongruence

3 . Endnotes

A. Sixty days would be a reasonable length of authorization for the treatment of infertility. [13]

4 . References

1. Leuprolide acetate prescribing information. Sandoz Inc. Princeton, NJ. June 2020.
2. Lupron Depot (3.75 mg) prescribing information. AbbVie Inc. North Chicago, IL. October 2023.
3. Lupron Depot (3-Month 11.25 mg) prescribing information. AbbVie Inc. North Chicago, IL. October 2023.
4. Friedman AJ, Harrison-Atlas D, Barbieri RL, et al. A randomized, placebo-controlled, double-blind study evaluating the efficacy of leuprolide acetate depot in the treatment of uterine leiomyomata. Fertil Steril 1989;51:251-256.
5. DRUGDEX System [Internet database]. Greenwood Village, Colorado: Thomson Micromedex. Updated periodically. Accessed July 22, 2024.
6. Lethaby A, Vollenhoven B, Sowter M. Pre-operative GnRH analogue therapy before hysterectomy or myomectomy for uterine fibroids. Cochrane Database Syst Rev. 2001;(2):CD000547.
7. Supprelin LA prescribing information. Endo USA. Malvern, PA. April 2022.
8. Ferrero, S., Barra, F. & Leone Roberti Maggiore, U. Current and Emerging Therapeutics for the Management of Endometriosis. Drugs 78, 995–1012 (2018).
9. Lupron Depot (7.5 mg, 22.5 mg, 30 mg, 45 mg) prescribing information. AbbVie Inc. North Chicago, IL. March 2024.
10. Eligard prescribing information. Tolmar Pharmaceuticals, Inc. Fort Collins, CO. May 2024.
11. Trelstar prescribing information. Verity Pharmaceuticals, Inc. Ewing, NJ. April 2024.
12. Practice bulletin no. 114: management of endometriosis. Obstet Gynecol. 2010 Jul; 116 (1): 223-36.
13. Per clinical consult with reproductive endocrinologist, April 10, 2013.
14. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN Compendium). Available at:

http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 31, 2022.
15. Lupron Depot-PED prescribing information. AbbVie Inc. North Chicago, IL. April 2023.
16. Hembree, Wylie C, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. "Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline." The Journal of clinical endocrinology and metabolism 94.9 (2009):3132-3154.
17. Coleman E, Bockting W, Botzer M et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. International Journal of Transgenderism. 13:165-232, 2011.
18. Triptodur prescribing information. Azurity Pharmaceuticals, Inc. Woburn, MA. November 2023.
19. Fensolvi prescribing information. Tolmar Inc. Fort Collins, CO. April 2023.
20. Camcevi Prescriber Information. Accord BioPharma, Inc. Raleigh, NC. November 2023.
21. Leuprolide Acetate Depot prescribing information. Cipla USA, Inc. Warren, NJ. November 2023.
22. Harrington, J, Palmert, M. Treatment of precocious puberty. UpToDate. 2022. https://www.uptodate.com/contents/treatment-of-precocious-puberty?search=central%20precocious%20puberty&source=search_result&selectedTitle=2~30&usage_type=default&display_rank=2. Accessed July 2, 2024.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228869
Guideline Name	Gonadotropin-Releasing Hormone Antagonists (Infertility Agents)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cetrotide (cetrorelix)
Controlled ovarian stimulation Indicated for the inhibition of premature LH surges in women undergoing controlled ovarian stimulation.
Drug Name: Generic ganirelix, Generic Fyremadel
Controlled ovarian stimulation Indicated for the inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation.

2 . Criteria

Product Name:Generic ganirelix*, Generic Fyremadel*	
Approval Length	6 month(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GANIRELIX ACETATE	GANIRELIX ACETATE SOLN PREFILLED SYRINGE 250 MCG/0.5ML	3009004010E520	Generic
FYREMADEL	GANIRELIX ACETATE SOLN PREFILLED SYRINGE 250 MCG/0.5ML	3009004010E520	Generic

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (ovarian stimulation)

AND

3 - Will be used in conjunction only with assisted reproductive technology (ART)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name:Cetrotide*	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CETROTIDE	CETRORELIX ACETATE FOR INJ KIT 0.25 MG	30090025106420	Brand

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (ovarian stimulation)

AND

3 - Will be used in conjunction only with assisted reproductive technology (ART)

AND

4 - Trial and failure, contraindication or intolerance to one of the following:

- Generic Ganirelix
- Generic Fyremadel

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

3 . References

1. Cetrotide Prescribing Information. EMD Serono, Inc. Rockland, MA. June 2024.
2. Ganirelix Acetate Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. May 2024.
3. Fyremadel Prescribing Information. Ferring Pharmaceuticals Inc. Parsippany, NJ. October 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233344
Guideline Name	Gonadotropins - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	3/1/2025
P&T Approval Date:	7/20/2001
P&T Revision Date:	8/15/2024

1 . Indications

Drug Name: Follistim AQ (follitropin beta)
Ovulation Induction Indicated for the induction of ovulation and pregnancy in anovulatory infertile women in whom the cause of infertility is functional and not due to primary ovarian failure. **Spermatogenesis Induction** Indicated for the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism (HH) in whom the cause of infertility is not due to primary testicular failure. **Ovarian Stimulation in association with Assisted Reproductive Technology** Indicated for pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycle.
Drug Name: Gonal-F (follitropin alfa)

Ovulation Induction Indicated for the induction of ovulation and pregnancy in oligo-anovulatory infertile women for whom the cause of infertility is functional and not due to primary ovarian failure.

Ovarian Stimulation in association with Assisted Reproductive Technology Indicated for the development of multiple follicles in ovulatory infertile women as part of an assisted reproductive technology (ART) cycle.

Spermatogenesis Induction Indicated for the induction of spermatogenesis in infertile men with primary and secondary hypogonadotropic hypogonadism for whom the cause of infertility is not due to primary testicular failure.

Drug Name: Gonal-F RFF (follitropin alfa)

Ovarian Stimulation in association with Assisted Reproductive Technology [1-5] Indicated for the development of multiple follicles in ovulatory infertile women as part of an assisted reproductive technology (ART) cycle.

Ovulation Induction Indicated for the induction of ovulation and pregnancy in oligo-anovulatory infertile women for whom the cause of infertility is functional and not due to primary ovarian failure.

Off Label Uses: Spermatogenesis Induction [6, 7] Used for the treatment of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

Drug Name: Gonal-F RFF Redi-ject (follitropin alfa)

Ovarian Stimulation in association with Assisted Reproductive Technology [1-5] Indicated for the development of multiple follicles in ovulatory women as part of an assisted reproductive technology (ART) cycle.

Ovulation Induction Indicated for the induction of ovulation and pregnancy in oligo-anovulatory women in whom the cause of infertility is functional and not due to primary ovarian failure.

Off Label Uses: Spermatogenesis Induction [6, 7] Used for the treatment of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

Drug Name: Menopur (menotropins)

Ovarian Stimulation in association with Assisted Reproductive Technology Indicated for the development of multiple follicles and pregnancy in ovulatory women as part of an Assisted Reproductive Technology (ART) cycle.

Off Label Uses: Ovulation Induction [6, 7] Used for the treatment of ovulation induction in patients with polycystic ovary syndrome who failed on clomiphene. The ovulation rate compared to Gonal-f was non-inferior, at rates of 85.7% and 85.5% respectively. [8] In other studies, rates of ovulation of 95% and pregnancy rates of 58% to 72% are demonstrated.

Because of its high cost, higher incidence of serious side effects, and difficult of administration menotropins are usually reserved to treat patients who have failed to respond to therapy with clomiphene. [9]

Spermatogenesis Induction [6, 7] Used for the treatment of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

2 . Criteria

Product Name:Follistim AQ	
Diagnosis	Ovulation Induction
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FOLLISTIM AQ	FOLLITROPIN BETA INJ 300 UNIT/0.36ML	30062030102020	Brand
FOLLISTIM AQ	FOLLITROPIN BETA INJ 600 UNIT/0.72ML	30062030102030	Brand
FOLLISTIM AQ	FOLLITROPIN BETA INJ 900 UNIT/1.08ML	30062030102040	Brand

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - Diagnosis of anovulatory infertility

AND

3 - Infertility is not due to primary ovarian failure

AND

4 - For induction of ovulation

AND

5 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name:Gonal-f, Gonal-f RFF, Gonal-f RFF Redi-ject, Menopur (off-label)	
Diagnosis	Ovulation Induction
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GONAL-F RFF	FOLLITROPIN ALFA FOR INJ 75 UNIT	30062030052115	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 450 UNIT	30062030052140	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 1050 UNIT	30062030052150	Brand
MENOPUR	MENOTROPINS FOR SUBCUTANEOUS INJ 75 UNIT	30062050002175	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 300 UNIT/0.5ML	3006203005D220	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 450 UNIT/0.75ML	3006203005D225	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 900 UNIT/1.5ML	3006203005D240	Brand

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - Diagnosis of anovulatory infertility

AND

3 - Infertility is not due to primary ovarian failure

AND

4 - For induction of ovulation

AND

5 - One of the following:

5.1 Trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [A]

OR

5.2 Patient has a condition that requires use of drug that contains both luteinizing hormone (LH) and follicle-stimulating hormone (FSH) (applies to Menopur only)

AND

6 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name:Gonal-f, Gonal-f RFF, Gonal-f RFF Redi-ject	
Diagnosis	Ovulation Induction
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GONAL-F RFF	FOLLITROPIN ALFA FOR INJ 75 UNIT	30062030052115	Brand

GONAL-F	FOLLITROPIN ALFA FOR INJ 450 UNIT	30062030052140	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 1050 UNIT	30062030052150	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 300 UNIT/0.5ML	3006203005D220	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 450 UNIT/0.75ML	3006203005D225	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 900 UNIT/1.5ML	3006203005D240	Brand

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - Submission of medical records (e.g., chart notes) confirming diagnosis of anovulatory infertility

AND

3 - Submission of medical records (e.g., chart notes) confirming infertility is not due to primary ovarian failure

AND

4 - For induction of ovulation

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [A]

AND

6 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name:Follistim AQ	
Diagnosis	Ovarian Stimulation
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FOLLISTIM AQ	FOLLITROPIN BETA INJ 300 UNIT/0.36ML	30062030102020	Brand
FOLLISTIM AQ	FOLLITROPIN BETA INJ 600 UNIT/0.72ML	30062030102030	Brand
FOLLISTIM AQ	FOLLITROPIN BETA INJ 900 UNIT/1.08ML	30062030102040	Brand

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - Diagnosis of infertility

AND

3 - For the development of multiple follicles (ovarian stimulation) in an ovulatory female patient participating in an Assisted Reproductive Technology (ART) program

AND

4 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name:Gonal-f, Gonal-f RFF, Gonal-f RFF Redi-ject, Menopur

Diagnosis	Ovarian Stimulation
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GONAL-F RFF	FOLLITROPIN ALFA FOR INJ 75 UNIT	30062030052115	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 450 UNIT	30062030052140	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 1050 UNIT	30062030052150	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 300 UNIT/0.5ML	3006203005D220	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 450 UNIT/0.75ML	3006203005D225	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 900 UNIT/1.5ML	3006203005D240	Brand
MENOPUR	MENOTROPINS FOR SUBCUTANEOUS INJ 75 UNIT	30062050002175	Brand

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - Diagnosis of infertility

AND

3 - For the development of multiple follicles (ovarian stimulation) in an ovulatory female patient participating in an Assisted Reproductive Technology (ART) program

AND

4 - One of the following:

4.1 Trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [B]

OR

4.2 Concomitant use with Follistim AQ is required (applies to Menopur only)

AND

5 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name:Gonal-f, Gonal-f RFF, Gonal-f RFF Redi-ject	
Diagnosis	Ovarian Stimulation
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GONAL-F RFF	FOLLITROPIN ALFA FOR INJ 75 UNIT	30062030052115	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 450 UNIT	30062030052140	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 1050 UNIT	30062030052150	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 300 UNIT/0.5ML	3006203005D220	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 450 UNIT/0.75ML	3006203005D225	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 900 UNIT/1.5ML	3006203005D240	Brand

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - Submission of medical records (e.g., chart notes) confirming diagnosis of infertility

AND

3 - For the development of multiple follicles (ovarian stimulation) in an ovulatory female patient participating in an Assisted Reproductive Technology (ART) program

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [B]

AND

5 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name:Follistim AQ	
Diagnosis	Male Hypogonadotropic Hypogonadism
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FOLLISTIM AQ	FOLLITROPIN BETA INJ 300 UNIT/0.36ML	30062030102020	Brand
FOLLISTIM AQ	FOLLITROPIN BETA INJ 600 UNIT/0.72ML	30062030102030	Brand
FOLLISTIM AQ	FOLLITROPIN BETA INJ 900 UNIT/1.08ML	30062030102040	Brand

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - One of the following:

- Diagnosis of male primary hypogonadotropic hypogonadism
- Diagnosis of male secondary hypogonadotropic hypogonadism

AND

3 - For induction of spermatogenesis

AND

4 - Infertility is not due to primary testicular failure

AND

5 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name:Gonal-f, Gonal-f RFF (off-label), Gonal-f RFF Redi-ject (off-label), Menopur (off-label)	
Diagnosis	Male Hypogonadotropic Hypogonadism
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GONAL-F RFF	FOLLITROPIN ALFA FOR INJ 75 UNIT	30062030052115	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 450 UNIT	30062030052140	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 1050 UNIT	30062030052150	Brand

GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 300 UNIT/0.5ML	3006203005D220	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 450 UNIT/0.75ML	3006203005D225	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 900 UNIT/1.5ML	3006203005D240	Brand
MENOPUR	MENOTROPINS FOR SUBCUTANEOUS INJ 75 UNIT	30062050002175	Brand

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - One of the following:

- Diagnosis of male primary hypogonadotropic hypogonadism
- Diagnosis of male secondary hypogonadotropic hypogonadism

AND

3 - For induction of spermatogenesis

AND

4 - Infertility is not due to primary testicular failure

AND

5 - Trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [C]

AND

6 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name:Gonal-f, Gonal-f RFF (off-label), Gonal-f RFF Redi-ject (off-label)	
Diagnosis	Male Hypogonadotropic Hypogonadism
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GONAL-F RFF	FOLLITROPIN ALFA FOR INJ 75 UNIT	30062030052115	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 450 UNIT	30062030052140	Brand
GONAL-F	FOLLITROPIN ALFA FOR INJ 1050 UNIT	30062030052150	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 300 UNIT/0.5ML	3006203005D220	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 450 UNIT/0.75ML	3006203005D225	Brand
GONAL-F RFF REDIJECT	FOLLITROPIN ALFA SUBCUTANEOUS SOLN PEN-INJ 900 UNIT/1.5ML	3006203005D240	Brand

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - Submission of medical records (e.g., chart notes) confirming one of the following:

- Diagnosis of male primary hypogonadotropic hypogonadism
- Diagnosis of male secondary hypogonadotropic hypogonadism

AND

3 - For induction of spermatogenesis

AND

4 - Submission of medical records (e.g., chart notes) confirming infertility is not due to primary testicular failure

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [C]

AND

6 - Prescribed by or in consultation with a reproductive endocrinologist

3 . Endnotes

A. There is no consensus definition of poor responder to gonadotropins in the setting of ovulation induction. [10-11, 13-15] One study looked at ovulation induction failure with gonadotropin specifically. [10] Poor response in this study was defined as maximum dose of 450 IU gonadotropin daily for 9 days and either: (i) < 4 oocytes obtained at oocyte retrieval, or (ii) cycle cancellation prior to oocyte retrieval because of poor follicular development (< 3 follicles of > 14 mm after 9-12 days of stimulation).
B. There is no consensus definition of poor responder to gonadotropins in the setting of ovarian stimulation in association with ART. [10-11, 13-15] The most cited definition of poor responders was: number of mature follicles < 2-5; number of mature oocytes retrieved < 3: single dominant follicle; mean daily gonadotropin dose > 300 IU; and total gonadotropin dose > 40 ampules. [10]
C. There is no consensus definition of poor responder to gonadotropins in the setting of spermatogenesis induction in men with hypogonadotropic hypogonadism. Outcomes measured for response include time to achieve first sperm, time to conception, and sperm concentration, but poor response was not well-defined. [12, 16] A combined analysis looked at four clinical trials and used the common efficacy outcome of spermatozoa concentration of greater than or equal 1.5 x 10^6 /mL. [12]
D. Sixty days would be a reasonable length of authorization for all of the indications. [20]

4 . References

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20. Per clinical consult with reproductive endocrinologist, April 10, 2013.

5 . Revision History

Date	Notes
2/26/2025	Quartz Comm copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-229087
Guideline Name	Growth Hormones - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand

NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- Infant is less than 4 months of age
- Infant has suspected GH deficiency based on clinical presentation (e.g., persistent neonatal hypoglycemia, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive, etc.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine

- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are less than 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is less than 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	Includes children who have undergone brain radiation. If patient is a T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency. NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal. *Approve at N DC list "SOMATROPPA".

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	Includes children who have undergone brain radiation. If patient is a T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency. *Approve at NDC list "SOMATROPPA”.

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- Infant is less than 4 months of age
- Suspected GHD based on clinical presentation (e.g., persistent neonatal hypoglycemia that is not responsive to treatment, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, etc.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine

- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are less than 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is less than 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Notes	Includes children who have undergone brain radiation. If patient is a T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency.

	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)

- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- Infant is less than 4 months of age
- Suspected GHD based on clinical presentation (e.g., persistent neonatal hypoglycemia that is not responsive to treatment, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, etc.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 Submission of medical records (e.g., chart notes) documenting all of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 One of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are less than 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is less than 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Notes	Includes children who have undergone brain radiation. If patient is a T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency.

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 3 MG	3010000380E110	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 3.6 MG	3010000380E115	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 4.3 MG	3010000380E120	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 5.2 MG	3010000380E125	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 6.3 MG	3010000380E130	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 7.6 MG	3010000380E135	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 9.1 MG	3010000380E140	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 11 MG	3010000380E145	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CART 13.3 MG	3010000380E150	Brand

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are less than 10 mcg/L

AND

2 - Patient is 1 year of age or older

AND

3 - Patient weight is 11.5 kg or greater

AND

4 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name:Skytrofa

Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 3 MG	3010000380E110	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 3.6 MG	3010000380E115	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 4.3 MG	3010000380E120	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 5.2 MG	3010000380E125	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 6.3 MG	3010000380E130	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 7.6 MG	3010000380E135	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 9.1 MG	3010000380E140	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 11 MG	3010000380E145	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CART 13.3 MG	3010000380E150	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name:Sogroya	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are less than 10 mcg/L

AND

2 - Patient is 2.5 years of age or older

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

AND

5 - Trial and failure, contraindication or intolerance to both of the following:

- Skytrofa
- Ngenla

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name:Sogroya

Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)

- Omnitrope (somatropin)

AND

5 - Trial and failure, contraindication or intolerance to both of the following:

- Skytrofa
- Ngenla

Product Name:Sogroya	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 Submission of medical records (e.g., chart notes) documenting all of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are less than 10 mcg/L

AND

2 - Patient is 2.5 years of age or older

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to both of the following:

- Skytrofa
- Ngenla

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name:Sogroya	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to both of the following:

- Skytrofa
- Ngenla

Product Name:Ngenla	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NGENLA	SOMATROGON-GHLA SOLUTION PEN-INJECTOR 24 MG/1.2ML (20 MG/ML)	3010001500D220	Brand
NGENLA	SOMATROGON-GHLA SOLUTION PEN-INJECTOR 60 MG/1.2ML (50 MG/ML)	3010001500D240	Brand

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male

- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are less than 10 mcg/L

AND

2 - Patient is 3 years of age or older

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name:Ngenla

Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NGENLA	SOMATROGON-GHLA SOLUTION PEN-INJECTOR 24 MG/1.2ML (20 MG/ML)	3010001500D220	Brand
NGENLA	SOMATROGON-GHLA SOLUTION PEN-INJECTOR 60 MG/1.2ML (50 MG/ML)	3010001500D240	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name:Norditropin Flexpro*, Omnitrope* [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPA".

Product Name:Norditropin Flexpro*, Omnitrope* [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand

NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPA".

Product Name:Genotropin, Humatrope [off-label], Nutropin AQ NuSpin [off-label],Saizen [off-label], Zomacton [off-label] [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope [off-label], Nutropin AQ NuSpin [off-label], Saizen [off-label], Zomacton [off-label] [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand

SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope [off-label], Nutropin AQ NuSpin [off-label], Saizen [off-label], Zomacton [off-label] [B, 11]	
Diagnosis	Prader-Willi Syndrome

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand

NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope [off-label], Nutropin AQ NuSpin [off-label], Saizen [off-label], Zomacton [off-label] [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand

SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Submission of medical records (e.g., chart notes) documenting both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 One of the following is below the 3rd percentile for gestational age (more than 2 SD below population mean):

- Birth weight
- Birth length

AND

2 - Height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal. *Approve at NDC list " SOMATROPPA”.

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPA".

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin [off-label] [B, 11], Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 One of the following is below the 3rd percentile for gestational age (more than 2 SD below the population mean):

- Birth weight
- Birth length

AND

2 - Height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)

• Omnitrope (somatropin)	
Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin [off-label] [B, 11], Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [28]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin [off-label] [B, 11], Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 Submission of medical records (e.g., chart notes) documenting one of the following is below the 3rd percentile for gestational age (more than 2 SD below the population mean):

- Birth weight
- Birth length

AND

2 - Submission of medical records (e.g., chart notes) documenting height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin [off-label] [B, 11], Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [28]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Documentation of both of the following:

- Patient is female
- Bone age less than 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Documentation of one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

2 - Height is below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal. *Approve at NDC list " SOMATROPPA".

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND
3 - Prescribed by or in consultation with an endocrinologist
Notes | *Approve at NDC list "SOMATROPPA".

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Documentation of both of the following:

- Patient is female
- Bone age less than 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Documentation of one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

2 - Height is below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton

Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton

Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Submission of medical records (e.g., chart notes) documenting both of the following:

- Patient is female
- Bone age less than 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Submission of medical records (e.g., chart notes) documenting one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

2 - Submission of medical records (e.g., chart notes) documenting height below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand

ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claim or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand

NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.*Approve at NDC list "S OMATROPPA".

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPA".

Product Name:Genotropin [off-label], Humatrope, Nutropin AQ NuSpin [off-label], Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name:Genotropin [off-label], Humatrope, Nutropin AQ NuSpin [off-label], Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin [off-label], Humatrope, Nutropin AQ NuSpin [off-label], Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin [off-label], Humatrope, Nutropin AQ NuSpin [off-label], Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand

GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Norditropin Flexpro* [off-label] [B, 11], Omnitrope* [off-label] [B, 11]	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.*Approve at NDC list "SOMATROPPA".

Product Name:Norditropin Flexpro* [off-label] [B, 11], Omnitrope* [off-label][B, 11]	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

Notes	*Approve at NDC list "SOMATROPPA".

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist

- Nephrologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand

HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand

NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 20-21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Documented deficiency of three of the following anterior pituitary hormones:

- Prolactin
- Adrenocorticotropic hormone (ACTH)
- Thyroid stimulating hormone (TSH)
- Follicle-stimulating hormone/luteinizing hormone (FSH/LH)

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase. *Approve at NDC list "SOMATROPPA".

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.*Approve at NDC list "SOMATROPPA".

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton [B, 21]	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand

SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand

NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Documented deficiency of three of the following anterior pituitary hormones:

- Prolactin
- ACTH
- TSH
- FSH/LH

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton [B, 21]	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton [B, 21]

Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand

SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Submission of medical records (e.g., chart notes) supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Submission of medical records (e.g., chart notes) documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Submission of medical records (e.g., chart notes) documenting deficiency of three of the following anterior pituitary hormones:

- Prolactin
- ACTH
- TSH
- FSH/LH

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton [B, 21]	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting evidence of ongoing monitoring within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)

• Omnitrope (somatropin)	
Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name:Norditropin Flexpro*, Omnitrope* [off-label]	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	

Approval Criteria

1 - One of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - One of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPA".

Product Name:Norditropin Flexpro*, Omnitrope* [off-label]	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand

NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5M	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPA".

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand

HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - One of the following: [21]

- Attained expected adult height

- Closed epiphyses on bone radiograph

AND

2 - One of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand

SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand

NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Documented deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPA".

Product Name:Norditropin Flexpro*, Omnitrope*	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPA".

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton [off-label] [B, 21]	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Documented deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton [off-label] [B, 21]	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand

HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton [off-label] [B, 21]	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Sogroya, Zomacton [off-label] [B, 21]	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand

ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting evidence of ongoing monitoring within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name:Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SEROSTIM	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 4 MG	30100020102118	Brand
SEROSTIM	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 5 MG	30100020102121	Brand
SEROSTIM	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 6 MG	30100020102125	Brand

Approval Criteria

1 - Diagnosis of HIV-associated wasting syndrome or cachexia [7, 15, 18, 19]

AND

2 - One of the following: [7, 15, 18, 19, C]

2.1 Unintentional weight loss of greater than 10% over the last 12 months

OR

2.2 Unintentional weight loss of greater than 7.5% over the last 6 months

OR

2.3 Loss of 5% body cell mass (BCM) within 6 months

OR

2.4 Body mass index (BMI) less than 20 kg/m^2

OR

2.5 All of the following

- Patient is male
- BCM less than 35% of total body weight
- BMI less than 27 kg/m^2

OR

2.6 All of the following

- Patient is female
- BCM less than 23% of total body weight
- BMI less than 27 kg/m^2

AND

3 - Nutritional evaluation since onset of wasting first occurred [7, 15, 18, 19]

AND

4 - Patient has not had weight loss as a result of other underlying treatable conditions (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes) [7, 15, 18, 19]

AND

5 - Anti-retroviral therapy has been optimized to decrease the viral load [7, 15, 18, 19]

Product Name:Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia
Approval Length	6 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SEROSTIM	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 4 MG	30100020102118	Brand
SEROSTIM	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 5 MG	30100020102121	Brand
SEROSTIM	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 6 MG	30100020102125	Brand

Approval Criteria

1 - Evidence of positive response to therapy (i.e., greater than or equal to 2% increase in body weight and/or BCM) [17, 18]

AND

2 - One of the following targets or goals has not been achieved: [17, 18]

- Weight
- BCM
- BMI

Product Name:Zorbtive	
Diagnosis	Short Bowel Syndrome
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZORBTIVE	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 8.8 MG	30100020102132	Brand

Approval Criteria

1 - Diagnosis of Short Bowel Syndrome [9, 16]

AND

2 - Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements) [9, 16]

AND

3 - Patient has not previously received 4 weeks of treatment with Zorbtive [9, 16]

Notes	NOTE: Treatment with Zorbtive will not be authorized beyond 4 weeks . Administration for more than 4 weeks has not been adequately studi ed.

Product Name:All Products	
Guideline Type	Prior Authorization, Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
SEROSTIM	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 4 MG	30100020102118	Brand
SEROSTIM	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 5 MG	30100020102121	Brand
SEROSTIM	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 6 MG	30100020102125	Brand
ZORBTIVE	SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 8.8 MG	30100020102132	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 3 MG	3010000380E110	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 3.6 MG	3010000380E115	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 4.3 MG	3010000380E120	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 5.2 MG	3010000380E125	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 6.3 MG	3010000380E130	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 7.6 MG	3010000380E135	Brand

SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 9.1 MG	3010000380E140	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CARTRIDGE 11 MG	3010000380E145	Brand
SKYTROFA	LONAPEGSOMATROPIN-TCGD FOR SUBCUTANEOUS INJ CART 13.3 MG	3010000380E150	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010000720D210	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010000720D220	Brand
SOGROYA	SOMAPACITAN-BECO SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010000720D230	Brand
NGENLA	SOMATROGON-GHLA SOLUTION PEN-INJECTOR 24 MG/1.2ML (20 MG/ML)	3010001500D220	Brand
NGENLA	SOMATROGON-GHLA SOLUTION PEN-INJECTOR 60 MG/1.2ML (50 MG/ML)	3010001500D240	Brand

NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Requests for coverage of growth hormone for the diagnosis of Idiopathic Short Stature (ISS) are not authorized and will not be approved. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [E]

Notes	Approval Length: N/A - Requests for non-approvable diagnoses shoul d not be approved

2 . Endnotes

A. Several recent review articles in the literature have suggested that GH stimulation tests should no longer be used to diagnose GHD. [13,14] The authors argue that GH stimulation test may have side effects, lack precision, accuracy, and do not predict response to GH therapy. It has been suggested that newer diagnostic procedures such as serum IGF-1, IGFBP-3 concentrations, genetic testing and neuroimaging could provide an alternative approach to the diagnosis of GHD in childhood.
B. Overall, there are no observable differences in the results obtained among the different preparations as long as the regimen follows currently approved daily injections. Many of the products are available in a variety of injection devices that are meant to make administration more appealing and easier. Currently, there is no evidence that clinical outcome differs among the various injection systems, although there may be patient and parent preferences for some of these devices. [11, 21]
C. Even a 5% weight loss in persons with HIV infection indicates a poor prognosis. [2]
D. Patients with HIV-associated wasting may begin an initial 12-week course of therapy with Serostim, 6 mg/day s.c. The clinician should monitor treatment responses by obtaining serial body weights and BCM measurements by BIA. A positive response to therapy probably should be considered as a 2% increase in body weight and/or BCM. Maintenance therapy may continue on a monthly basis as long as wasting is still evident. Once BCM has normalized, therapy can be stopped, with the patient being observed for an 8-week period. Over these 8 weeks, body weight, BCM, and any appearance of wasting symptoms can be monitored. If wasting reappears, therapy can be restarted. [17]
E. Guidelines for idiopathic short stature recommend against the routine use of GH in every child with height standard deviation score ≤ - 2.25. [23]
F. When GHD is congenital and near complete, the diagnosis is relatively easy to confirm because affected children present with severe growth failure, delayed bone age, and

very low serum concentrations of GH, IGF-1, and IGFBP-3 [8]. For patients with all of these clinical characteristics, it is reasonable to make the diagnosis of GHD without performing GH stimulation testing. [29]

G. Measurements of IGF-1 and IGFBP-3 have shown comparable diagnostic performance with growth hormone stimulation tests and are valuable for patient`s convenience and ease of performance and can be useful in the workup of growth hormone deficiency. [30]

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4 . Revision History

Date	Notes
12/20/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-228870
Guideline Name	Harvoni (ledipasvir/sofosbuvir) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Harvoni (ledipasvir/sofosbuvir)
Chronic Hepatitis C (CHC) Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV)]: - Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis; - Genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin; - Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin

2 . Criteria

Product Name:Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA less than 6 Million IU/mL

Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Pre-treatment HCV RNA less than 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following (applies to brand ledipasvir/sofosbuvir only):

7.1 Both of the following:

7.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name:Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA less than 6 Million IU/mL
Approval Length	8 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Submission of medical records documenting pre-treatment HCV RNA less than 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA greater than or equal to 6 Million IU/mL
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Pre-treatment HCV RNA greater than or equal to 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following (applies to brand ledipasvir/sofosbuvir only):

7.1 Both of the following:

7.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name:Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA greater than or equal to 6 Million IU/mL
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Submission of medical records documenting pre-treatment HCV RNA greater than or equal to 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Treatment-Naive or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced (No Decompensated Cirrhosis)
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6

AND

2 - One of the following:

- Patient is treatment-naive
- Patient has prior failure to peginterferon alfa plus ribavirin treatment
- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Both of the following:

6.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name:Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Treatment-Naive or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced (No Decompensated Cirrhosis)
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6

AND

2 - One of the following:

- Patient is treatment-naive
- Patient has prior failure to peginterferon alfa plus ribavirin treatment

- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Post-Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient is a liver transplant recipient

AND

3 - One of the following:

3.1 Patient is without cirrhosis or has compensated cirrhosis (Child-Pugh Class A)

OR

3.2 Both of the following:

- Patient has decompensated cirrhosis (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Both of the following:

6.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name:Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Post-Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient is a liver transplant recipient

AND

3 - One of the following:

3.1 Patient is without cirrhosis or has compensated cirrhosis (Child-Pugh Class A)

OR

3.2 Both of the following:

- Patient has decompensated cirrhosis (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis - Ribavirin Eligible
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name:Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis - Ribavirin Eligible
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis; Ribavirin Ineligible OR Prior Sovaldi or NS5A-Based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - One of the following:

3.1 Patient is ribavirin ineligible

OR

3.2 Both of the following:

- Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name:Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis; Ribavirin Ineligible OR Prior Sovaldi or NS5A-Based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - One of the following:

3.1 Patient is ribavirin ineligible

OR

3.2 Both of the following:

- Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

1. Harvoni Prescribing Information. Gilead Sciences, Inc. Foster City, CA. March 2020.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228608
Guideline Name	Healthcare Reform Copay Waiver Review
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

Note:

The intent of this policy is to allow patients to receive medications/products that are not on the Healthcare Reform (HCR) preventative drug list (but are in the same drug class) at no cost-share. First and foremost, the patient must meet the basic HCR criteria (as described below) in order to qualify for zero cost-share.

1 . Criteria

Product Name:Fluoride supplementation products	
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Healthcare Reform Exceptions			

Health Care Reform Exceptions			
Fluoride supplementation products			
Healthcare			
HCR			

Approval Criteria

1 - Patient is between 6 months of age to 4 years of age*

AND

2 - Requested product is a prescription (single ingredient only) oral fluoride supplementation product (does not include topical fluoride products such as toothpaste or rinses, etc.)

AND

3 - There is a clinical reason why the patient cannot take two products on the HCR preventive drug list** (e.g., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)

Notes	*Benefit exclusion if age not met. **The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document.

Product Name:Folic acid supplementation products	
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Healthcare Reform Exceptions			
Health Care Reform Exceptions			

Folic acid supplementation products			
Healthcare			
HCR			

Approval Criteria

1 - Patient is of childbearing potential who is planning pregnancy*

AND

2 - Requested product is a prescription or OTC folic acid product (with prescription), including prenatal vitamins containing folic acid*

AND

3 - Requested product contains between 0.4 mg to 0.8 mg of folic acid**

AND

4 - There is a clinical reason why the patient cannot take two products on the HCR preventive drug list** (e.g., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)

Notes	*Benefit exclusion if not for childbearing or for multivitamins without folic acid. **Greater than 0.8mg is allowed for medical necessity. ***The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document.

Product Name:Aspirin	
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

Healthcare Reform Exceptions			
Health Care Reform Exceptions			
Aspirin			
Healthcare			
HCR			

Approval Criteria

1 - Patient meets the following*:

1.1 Patient is using 81 mg aspirin for the prevention of morbidity and mortality from preeclampsia

AND

1.2 Requested product is a single agent oral OTC aspirin product (with prescription) (but does not include prescription aspirin products, non-oral aspirin products, or aspirin strengths greater than 81 mg)

Notes	*Benefit exclusion if any criterion is not met.

Product Name:Immunizations	
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Healthcare Reform Exceptions			
Health Care Reform Exceptions			
Immunizations			
Heplisav			
Zostavax			

Shingrix			
Healthcare			
HCR			

Approval Criteria

1 - Requested product is a single-entity or combination vaccination for one of the following:**

- Diphtheria
- Haemophilus influenzae type B (applies only to children less than 6 years of age)*
- Hepatitis A
- Hepatitis B (Heplisav B applies only to adults ages 18 years and older)*
- Herpes zoster (Shingrix applies to adults ages 19 years and older)*
- Human papillomavirus (applies only to children and adults 9 years to 45 years of age)*
- Polio
- Influenza (Flumist applies only to children and adults 2 years through 49 years of age. Fluzone HD Quad, Fluad Quad applies only to adults ages 65 years and older)*
- Measles
- Mumps
- Rubella
- Meningococcal infections
- Pertussis
- Pneumococcal infections
- Respiratory Syncytial Virus ([Abrysvo applies to pregnant individuals at 32 through 36 weeks gestational age AND adults 60 years and older] [Arexvy applies only to adults 60 years and older])
- Rotavirus (applies only to children less than 8 months)*
- Tetanus
- Varicella

OR

2 - All of the following:

2.1 Requested product is for Dengvaxia vaccine:

AND

2.2 Member is between ages 9-16 living in a dengue endemic area (endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau)***

AND

2.3 Member has a laboratory confirmation of a previous dengue infection

OR

3 - All of the following:

3.1 Requested product is for Monkey Pox (JYNNEOS) vaccine

AND

3.2 Member is 18 years of age or older and has risk factors for Mpox infection^

Notes	*Benefit exclusion if age not met. **This list excludes vaccines not listed in the Advisory Committee on Immunization Practices (ACIP) Immunization Schedules (http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html). ***For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see: https://www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm and https://www.cdc.gov/dengue/vaccine/hcp/index.html ^For risk factors for Mpox infection see: Use of JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating) for Preexposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 | MMWR (cdc.gov) OR Adult Immunization Schedule Notes | CDC

Product Name:Bowel preparation agents for colorectal cancer screening [E]	
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Healthcare Reform Exceptions			
Health Care Reform Exceptions			

Bowel preparation agents for colorectal cancer screening			
Healthcare			
HCR			

Approval Criteria

1 - Requested product is a prescription bowel preparation agent used for primary preventative colorectal cancer screening (e.g., patient does not have a previous history of adenomatous polyps or previous colorectal cancer)*

AND

2 - There is a clinical reason why the patient cannot take two generic products on the HCR preventive drug list** (e.g., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response). (Some examples of generic bowel prep products include: TriLyte, Gavilyte, PEG-3350/electrolytes)

AND

3 - Quantity requested does not exceed the QL of two primary preventive bowel prep products per year***

Notes	*Benefit exclusion if not for cancer screening. **The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document. ***If a patient has an intolerance, allergic reaction, or an inadequate response to one of the products on the HCR preventative drug list, then the quantity limits will not apply for one time only per drug category (to allow for another product to be tried on the HCR preventative drug list).

Product Name:Erythromycin 0.5% ophthalmic ointment	
Approval Length	1 Month: Authorization will be issued for zero copay with deductible bypass for up to 1 month
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

ERYTHROMYCIN	ERYTHROMYCIN OPHTH OINT 5 MG/GM	86101025004210	Generic
Healthcare			
HCR			

Approval Criteria

1 - Member or health care provider intends to administer medication to newborn for the prophylaxis of gonococcal ophthalmia*

OR

2 - Newborn is 0-1 month of age**

Notes	*Please note, requests may be submitted before the infant's birth, and could be requested under the mother's account. **Benefit exclusion if age exceeded. This program is designed to meet Health Care Reform requirements which require coverage of erythromycin 0.5% ophthalmic ointment at zero dollar cost share if being used for primary prevention of gonococcal ophthalmia neonatorum (GON) and criteria are met. [H] The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document.

Product Name:Brand Truvada 200-300 mg, Generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg, Brand Viread 300mg, generic tenofovir disoproxil fumarate 300mg, Descovy	
Approval Length	12 Months: Authorization will be issued for zero copay with deductible bypass for 12 months
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
TRUVADA	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TAB 200-300 MG	12109902300320	Brand
TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE TAB 300 MG	12108570100320	Generic
DESCOVY	EMTRICITABINE-TENOFOVIR ALAFENAMIDE FUMARATE TAB 200-25 MG	12109902290320	Brand
VIREAD	TENOFOVIR DISOPROXIL FUMARATE TAB 300 MG	12108570100320	Brand

EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TAB 200-300 MG	12109902300320	Generic
Healthcare			
HCR			

Approval Criteria

1 - Member is taking as effective antiretroviral therapy for pre-exposure prophylaxis (PrEP)

AND

2 - One of the following:

2.1 Request is for generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg or generic tenofovir disoproxil fumarate 300mg

OR

2.2 History of contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg (Applies to Brand Truvada 200-300 mg and Descovy only)

OR

2.3 History of contraindication or intolerance to generic tenofovir disoproxil fumarate 300mg (Applies to Brand Viread 300mg only)

Notes	This program is designed to meet Health Care Reform requirements which require coverage of effective HIV Prep regimens at zero dollar c ost share if being used for pre-exposure prophylaxis (PrEP) and criteri a are met. [I] *The HCR preventive drug list is posted at: https://uhgaz ure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS% 20Guidelines/Healthcare%20Reform%20Supporting%20Document.

Product Name:Apretude	
Approval Length	12 Months: Authorization will be issued for zero copay with deductible bypass for 12 months
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
APRETUDE	CABOTEGRAVIR IM EXTENDED RELEASE SUSP 600 MG/3ML	1210301000G120	Brand

Approval Criteria

1 - Member is taking as effective antiretroviral therapy for pre-exposure prophylaxis (PrEP)

AND

2 - One of the following:

2.1 History of contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg, generic tenofovir disoproxil fumarate 300mg, or Descovy

OR

2.2 Provider attests to both of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens
- Patient would be adherent to testing and dosing schedule

Notes	This program is designed to meet Health Care Reform requirements which require coverage of effective HIV Prep regimens at zero dollar c ost share if being used for pre-exposure prophylaxis (PrEP) and criteri a are met. [I] *The HCR preventive drug list is posted at: https://uhgaz ure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS% 20Guidelines/Healthcare%20Reform%20Supporting%20Document.

Product Name:Arimidex (anastrozole) 1 mg, Aromasin (exemestane) 25 mg, Evista (raloxifene) 60 mg, Soltamox (tamoxifen) solution, Tamoxifen 20 mg tablets	
Approval Length	60 Months: Authorization will be issued for zero copay with deductible bypass for a total of up to 60 months (please determine if member has already received some length of therapy and if so subtract from total approval period).
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

EVISTA	RALOXIFENE HCL TAB 60 MG	30053060100320	Brand
RALOXIFENE HYDROCHLORIDE	RALOXIFENE HCL TAB 60 MG	30053060100320	Generic
TAMOXIFEN CITRATE	TAMOXIFEN CITRATE TAB 20 MG (BASE EQUIVALENT)	21402680100320	Generic
SOLTAMOX	TAMOXIFEN CITRATE ORAL SOLN 10 MG/5ML (BASE EQUIVALENT)	21402680102020	Brand
EXEMESTANE	EXEMESTANE TAB 25 MG	21402835000320	Generic
AROMASIN	EXEMESTANE TAB 25 MG	21402835000320	Brand
Healthcare			
HCR			
ANASTROZOLE	ANASTROZOLE TAB 1 MG	21402810000310	Generic

Approval Criteria

1 - Member is greater than or equal to 35 years of age*

AND

2 - Member has no prior diagnosis of any of the following:*

- breast cancer
- ductal carcinoma in situ (DCIS)

AND

3 - Member has no history of thromboembolic events (e.g.- deep venous thrombosis, pulmonary embolus, stroke or transient ischemic attack)*

AND

4 - Member has an estimated 5 year risk of breast cancer based on a breast cancer risk assessment tool of greater than or equal to 3% [11]*

AND

5 - One of the following:

5.1 Request is for tamoxifen 20 mg once daily

OR

5.2 Both of the following:

5.2.1 Member is post-menopausal

AND

5.2.2 One of the following:

5.2.2.1 Request is for raloxifene 60 mg once daily, exemestane 25 mg once daily, or anastrozole 1 mg once daily

OR

5.2.2.2 Request is for brand name Evista 60 mg, Aromasin 25 mg, and Arimidex 1 mg once daily and member has had failure, contraindication or adverse reaction to generic raloxifene, exemestane, or anastrozole

OR

5.3 Both of the following:

5.3.1 Request is for Soltamox 20 mg once daily*

AND

5.3.2 Member has had failure, contraindication or adverse reaction to tamoxifen tablets

Notes	*Benefit exclusion if age not met or has prior cancer diagnosis or has t hromboembolic events or less than 3% risk factor or requesting a diffe rent strength. This program is designed to meet Health Care Reform r equirements which require coverage of tamoxifen tablets, Soltamox (t amoxifen) solution, Evista (raloxifene), Aromasin (exemestane), and A

	rimidex (anastozole) at zero dollar cost share if being used for primary prevention of breast cancer and criteria are met.

2 . Endnotes

A. Important Risk Factors for Breast Cancer [5]: (1) Family history of breast or ovarian cancer (especially among first-degree relatives and onset before age 50 years); (2) History of atypical hyperplasia; (3) Non-malignant high-risk breast lesions; (4) Previous breast biopsy; (5) Extremely dense breast tissue; (6) Increasing age; (7) Race or ethnicity; (8) Age at menarche; (9) Age at first live childbirth; (10) Ductal carcinoma in situ (DCIS); (11) Lobular carcinoma in situ (LCIS); (12) Body mass index; (13) Menopause status or age; (14) Estrogen and progestin use; (15) Smoking; (16) Alcohol use; (17) Physical activity; (18) Diet.

B. The Affordable Care Act (ACA) requires private insurers to cover certain preventive services without any patient cost-sharing (i.e., copayments) when they are delivered by a network provider. The Department of Health and Human Services (HHS) has recognized several recommending bodies (e.g., United States Preventive Services Task Force [USPSTF], Advisory Committee on Immunization Practices [ACIP] http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html, Health Resources and Services Administration [HRSA]) who have identified several medication categories that fall within the preventive health mandate.

C. OptumRx has developed a Healthcare Reform Preventative Drug List posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document that identifies which products are eligible for coverage without patient copayment. Some products may be excluded (such as brand oral contraceptives) unless the patient meets the criteria in this exceptions policy.

D. Here is a brief summary of the exceptions allowed in this policy (provided the patient meets all of the specified criteria): (1) The fluoride supplementation exception allows for brand name products at no cost-share, but not combination products; (2) The folic acid exception allows for brand name and Rx products at no cost-share; (3) The smoking cessation exception allows for Nicotrol Inhaler, Nicotrol NS, and brand Zyban at no cost-share, but not additional quantities beyond the QLs; all other covered tobacco cessation products for members ages 18 years and older and not to exceed listed QLs; (4) The contraceptives exception allows for brand name products at no cost-share; (5) The bowel preparation agent exception allows for brand name Rx products at no cost-share but not beyond the QL; and (6) The statin exception allows for atorvastatin 10 mg or 20 mg, or simvastatin 5 mg, 10 mg, 20 mg, or 40mg generics at no cost-share. Other moderate to low dose statins include: pravastatin 10 mg, 20 mg, 40 mg, or 80 mg, fluvastatin 20 mg or 40 mg, pitavastatin 1 mg or 2 mg or 4 mg, rosuvastatin 5 mg or 10 mg.

E. Bowel Preparation Agents: It is important to distinguish between a screening and a surveillance or diagnostic colonoscopy. Screening is performed in asymptomatic patients with no history of colon cancer, polyps, and/or gastrointestinal disease. [1] Whereas, a surveillance colonoscopy can be performed at varying ages and intervals based on the patient’s personal history of colon cancer, polyps, and/or gastrointestinal disease. Patients with a history of colon polyp(s) are not recommended for a screening

colonoscopy, but for a surveillance colonoscopy. Per the USPSTF, when the screening test results in the diagnosis of clinically significant colorectal adenomas or cancer, the patient will be followed by a surveillance regimen, and recommendations for screening are no longer applicable. [6] According to the USPSTF, routine colorectal cancer screening is now recommended in adults beginning at age 45 and continuing only until age 75. The American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology jointly recommended screening for colorectal cancer beginning at 45 years of age by 1) high-sensitivity FOBT or fecal immunochemical testing annually, 2) flexible sigmoidoscopy every 5 years, 3) CT colonography (virtual colonoscopy) every 5 years, 4) colonoscopy every 10 years, or 5) fecal DNA at an unspecified interval. Based on the collective information above, we have a quantity limit in place of two bowel preparation agents per year. (This quantity limit will not apply if patient was intolerant to, had an allergic reaction, or an inadequate response to one of the bowel prep products on the HCR preventative drug list.)

F. Breast Cancer Prevention: The USPSTF recommends that clinicians engage in shared, informed decision-making with women who are at increased risk for breast cancer about medications to reduce their risk. [5] For women who are at an increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene. The USPSTF recommends against the routine use of medications, such as tamoxifen or raloxifene, for risk reduction of primary breast cancer in women who are not at increased risk for breast cancer. The updated STAR trial results show diminished benefits of raloxifene compared to tamoxifen after cessation of therapy, making it a preferred risk reduction choice for most post-menopausal women desiring non-surgical risk reduction therapy. However, consideration of toxicity (e.g., endometrial cancer or uterine bleeding) may still lead to the choice of raloxifene over tamoxifen in some women.
G. Gonococcal Ophthalmia Neonatorum (GON) Prevention: The USPSTF recommends prophylactic ocular topical medication for all newborns to prevent gonococcal ophthalmia neonatorum (GON). [17] GON can cause corneal scarring, ocular perforation, and blindness as early as 24 hours after birth. Erythromycin ophthalmic ointment is the only FDA approved drug for the prophylaxis of GON. Ocular prophylaxis of newborns is mandated in most states and is considered standard neonatal care.
H. The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. [19] Once-daily oral treatment with Truvada is the only formulation of PrEP approved by the US Food and Drug Administration (FDA) for use in the United States in persons at risk of sexual acquisition of HIV infection. However, several studies reviewed by the USPSTF found that tenofovir disoproxil fumarate alone was also effective as PrEP, and CDC guidelines note that, given these trial data, tenofovir disoproxil fumarate alone can be considered as an alternative regimen for high-risk heterosexually active men and women and persons who inject drugs. [19, 20]
I. The USPSTF recommends that clinicians offer to prescribe risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, to women who are at increased risk for breast cancer and at low risk for adverse medication effects. (B recommendation) The USPSTF recommends against the routine use of risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, in women who are not at increased risk for breast cancer. (D recommendation) This recommendation applies to asymptomatic women 35 years and older, including women with previous benign breast lesions on biopsy (such as atypical ductal or lobular hyperplasia and lobular carcinoma in situ). This recommendation does not apply to women who have a current or previous diagnosis of breast cancer or ductal carcinoma in situ.

J. The USPSTF recommends for children younger than 5 years of age, that primary care clinicians prescribe oral fluoride supplementation starting at age 6 months for children whose water supply is deficient in fluoride.

3 . References

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4 . Revision History

Date	Notes
11/8/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-228633
Guideline Name	Healthcare Reform Copay Waiver Review - Contraceptives
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

Note:

The intent of this policy is to allow patients to receive medications/products that are not on the Healthcare Reform (HCR) preventative drug list (but are in the same drug class) at no cost-share. First and foremost, the patient must meet the basic HCR criteria (as described below) in order to qualify for zero cost-share.

1 . Criteria

Product Name:Contraceptives [A]	
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Healthcare Reform Exceptions			

Health Care Reform Exceptions			
Contraceptives			
Healthcare			
HCR			
Contraceptive			

Approval Criteria

1 - For medical necessity requests, to waive cost-sharing for a medication not included on a zero cost-sharing coverage list* BOTH of the following must be met:

1.1 Patient is using the prescribed drug for contraception**

AND

1.2 The requested product is medically necessary***

Notes	*Zero cost share contraceptive coverage lists are available at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document. FDA Contraceptive Methods available at: https://www.fda.gov/consumers/free-publications-women/birth-control. **Benefit exclusion if not for contraception. ***Any justification of medical necessity/appropriateness provided by the prescriber is adequate to approve access of a preferred product at $0 cost share, in accordance with the ACA's contraceptive mandate.

2 . Endnotes

A. Oral Contraceptives: In order to receive an oral contraceptive at zero cost-share, a woman must be of childbearing potential and must be requesting an oral contraceptive for contraception (and not for another use) or if provider states medical necessity (as well as meeting the other criteria noted at the beginning of the policy). In addition, the 21 or 28 day oral contraceptive packs should not be approved for continuous use because there are continuous use products already on the Healthcare Reform Preventative Drug List posted at:

https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document.

3 . Revision History

Date	Notes
11/7/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-233387
Guideline Name	Hemangeol (propranolol hydrochloride oral solution)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	1/17/2024
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Hemangeol (propranolol hydrochloride oral solution)
Infantile hemangioma Indicated for the treatment of proliferating infantile hemangioma requiring systemic therapy.

2 . Criteria

Product Name:Hemangeol	
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HEMANGEOL	PROPRANOLOL HCL ORAL SOLN 4.28 MG/ML (3.75 MG/ML BASE EQUIV)	33100040102080	Brand

Approval Criteria

1 - Diagnosis of proliferating infantile hemangioma

AND

2 - Patient is less than or equal to 12 months of age [A]

Product Name:Hemangeol	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HEMANGEOL	PROPRANOLOL HCL ORAL SOLN 4.28 MG/ML (3.75 MG/ML BASE EQUIV)	33100040102080	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in size, absence of functional impact, tissue softening)

AND

2 - Patient is less than or equal to 18 months of age [A]

3 . Endnotes

A. Treatment typically is continued for at least 6 months and often is maintained until 12 months of age (occasionally longer). [2]

4 . References

1. Hemangeol Prescribing Information. Pierre Fabre Pharmaceuticals, Inc. Parsippany, NJ. June 2021.
2. Krowchuk DP, Frieden IJ, Mancini AJ, et al. Clinical Practice Guideline for the Management of Infantile Hemangiomas. Pediatrics. 2018;143(1):e20183475.

5 . Revision History

Date	Notes
3/13/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-228655
Guideline Name	Hereditary Angioedema Agents (HAE) Quantity Limit Override
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Berinert (C1 esterase inhibitor [Human])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute abdominal, facial, or laryngeal attacks of HAE in adult and adolescent patients. The safety and efficacy of Berinert for prophylactic therapy have not been established.
Drug Name: Firazyr (icatibant)
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of HAE in adults 18 years of age and older.
Drug Name: Sajazir (icatibant)
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.
Drug Name: Kalbitor (ecallantide)

Acute treatment of Hereditary Angioedema (HAE) Indicated for treatment of acute attacks of HAE in patients 12 years of age and older.
Drug Name: Ruconest (C1 esterase inhibitor [Recombinant])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks in adult and adolescent patients with HAE. Limitation of Use: Effectiveness was not established in HAE patients with laryngeal attacks.

2 . Criteria

Product Name:Brand Firazyr, Generic icatibant, Sajazir, Ruconest, Kalbitor, Berinert	
Approval Length	3 month(s)
Guideline Type	Quantity Limit Override

Product Name	Generic Name	GPI	Brand/Generic
SAJAZIR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
FIRAZYR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Brand
ICATIBANT ACETATE	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
RUCONEST	C1 ESTERASE INHIBITOR (RECOMBINANT) FOR IV INJ 2100 UNIT	85802022102130	Brand
KALBITOR	ECALLANTIDE INJ 10 MG/ML	85840030002020	Brand
BERINERT	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ KIT 500 UNIT	85802022006420	Brand

Approval Criteria

1 - Prescriber attests patient has 3 or more acute HAE attacks per month (document number of attacks per month if available)

AND

2 - Prescriber attests patient has been evaluated for the use of prophylactic therapy

AND

3 - One of the following*:

3.1 For Kalbitor, requested quantity does not exceed the ceiling limit of 48 vials per 30 days. Note to provider: Ceiling limit is based on the quantity sufficient for the treatment of 8 acute attacks per month.

OR

3.2 For Brand Firazyr, generic icatibant, or Sajazir, requested quantity does not exceed the ceiling limit of 24 syringes [72 mL] per 30 days. Note to provider: Ceiling limit is based on the quantity sufficient for the treatment of 8 acute attacks per month.

OR

3.3 For Ruconest, requested quantity does not exceed the ceiling limit of 32 vials per 30 days. Note to provider: Ceiling limit is based on the quantity sufficient for the treatment of 8 acute attacks per month.

OR

3.4 For Berinert, requested quantity does not exceed the ceiling limit of 32 vials per 30 days. Note to provider: Ceiling limit is based on the quantity sufficient for the treatment of 8 acute attacks per month.

Notes	Approve requests to MDD ceiling limits. Refer to background table for ceiling limits. *If all criteria above are met EXCEPT for the ceiling limit criterion, issue a partially favorable decision (i.e. approve to ceiling limit and deny quantities above ceiling limit for medical necessity). Denied quantities are reviewed on appeal.

3 . Background

Benefit/Coverage/Program Information

Ceiling Limits for HAE Agents

Ceiling Limits for HAE Agents	
Drug Name	**Ceiling Limit** (Amount sufficient to provide coverage for up to 8 acute attacks per month based on MDD)
Berinert	MDD = 1.1 (32 vials per 30 days)
Brand Firazyr Sajazir generic icatibant	MDD = 2.4 (24 syringes [72 mL] per 30 days)
Ruconest	MDD = 1.1 (32 vials per 30 days)
Kalbitor	MDD = 1.6 (48 vials per 30 days)

4 . References

1. Berinert Prescribing Information. CSL Behring, LLC. Kankakee, IL. September 2021.
2. Ruconest Prescribing Information. Pharming Healthcare Inc. Bridgewater, NJ. April 2020.
3. Firazyr Prescribing Information. Shire Orphan Therapies LLC. Lexington, MA. October 2021.
4. Kalbitor Prescribing Information. Dyax Corp. Lexington, MA. November 2021.
5. Sajazir Prescribing Information. Cipla Ltd., India. May 2022.

Prior Authorization Guideline

Guideline ID	GL-233314
Guideline Name	Hereditary Angioedema Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/16/2025
P&T Approval Date:	2/17/2009
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Berinert (C1 esterase inhibitor [Human])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute abdominal, facial, or laryngeal attacks of HAE in adult and adolescent patients. The safety and efficacy of Berinert for prophylactic therapy have not been established.
Drug Name: Cinryze (C1 esterase inhibitor [Human])
Prophylaxis of Hereditary Angioedema (HAE) Indicated for routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients (6 years old and above) with HAE. **Off Label Uses: Acute treatment of Hereditary Angioedema (HAE)** Following treatment with nanofiltered C1 inhibitor concentrate (Cinryze) for an acute attack, the median time to response was 30 minutes in 82 patients with HAE. [3]

Drug Name: Firazyr (icatibant)
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of HAE in adults 18 years of age and older.
Drug Name: Haegarda (C1 esterase inhibitor [Human])
Prophylaxis of Hereditary Angioedema (HAE) Indicated for routine prophylaxis to prevent HAE attacks in patients 6 years of age and older.
Drug Name: Kalbitor (ecallantide)
Acute treatment of Hereditary Angioedema (HAE) Indicated for treatment of acute attacks of HAE in patients 12 years of age and older.
Drug Name: Orladeyo (berotralstat)
Prophylaxis of Hereditary Angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older. Limitations of Use: The safety and effectiveness of ORLADEYO for the treatment of acute HAE attacks have not been established. ORLADEYO should not be used for treatment of acute HAE attacks. Additional doses or doses of ORLADEYO higher than 150 mg once daily are not recommended due to the potential for QT prolongation.
Drug Name: Ruconest (C1 esterase inhibitor [Recombinant])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks in adult and adolescent patients with HAE. Limitation of Use: Effectiveness was not established in HAE patients with laryngeal attacks.
Drug Name: Takhzyro (lanadelumab-flyo)
Prophylaxis of Hereditary Angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older.
Drug Name: Sajazir (icatibant)
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

2 . Criteria

Product Name:Cinryze, Haegarda, Orladeyo, Takhzyro	
Diagnosis	Prophylaxis of HAE attacks

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CINRYZE	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500 UNIT	85802022002120	Brand
HAEGARDA	C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 2000 UNIT	85802022002130	Brand
HAEGARDA	C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 3000 UNIT	85802022002140	Brand
TAKHZYRO	LANADELUMAB-FLYO INJ 300 MG/2ML (150 MG/ML)	85842040202020	Brand
ORLADEYO	BEROTRALSTAT HCL CAP 110 MG	85840010200120	Brand
ORLADEYO	BEROTRALSTAT HCL CAP 150 MG	85840010200130	Brand
TAKHZYRO	LANADELUMAB-FLYO SOLN PREF SYRINGE 300 MG/2ML (150 MG/ML)	8584204020E520	Brand
TAKHZYRO	LANADELUMAB-FLYO SOLN PREF SYRINGE 150 MG/ML	8584204020E510	Brand

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A, E]:

2.1 Diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal

- C1-INH functional level below the lower limit of normal

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 Normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For prophylaxis against HAE attacks [3]

AND

4 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

AND

5 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze and Haegarda only)
- Patient is 12 years of age or older (applies to Orladeyo only)
- Patient is 2 years of age or older (applies to Takhzyro only)

AND

6 - One of the following:

6.1 Trial and failure, contraindication or intolerance to one of the following: (applies to Cinryze only)

- Orladeyo
- Haegarda
- Takhzyro

OR

6.2 For continuation of prior therapy (applies to Cinryze only)

AND

7 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name:Cinryze, Haegarda, Orladeyo, Takhzyro	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CINRYZE	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500 UNIT	85802022002120	Brand

HAEGARDA	C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 2000 UNIT	85802022002130	Brand
HAEGARDA	C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 3000 UNIT	85802022002140	Brand
TAKHZYRO	LANADELUMAB-FLYO INJ 300 MG/2ML (150 MG/ML)	85842040202020	Brand
ORLADEYO	BEROTRALSTAT HCL CAP 110 MG	85840010200120	Brand
ORLADEYO	BEROTRALSTAT HCL CAP 150 MG	85840010200130	Brand
TAKHZYRO	LANADELUMAB-FLYO SOLN PREF SYRINGE 300 MG/2ML (150 MG/ML)	8584204020E520	Brand
TAKHZYRO	LANADELUMAB-FLYO SOLN PREF SYRINGE 150 MG/ML	8584204020E510	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in the number or rate of HAE attacks while on therapy)

AND

2 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

Product Name:Cinryze [off-label], Brand Firazyr, Generic icatibant, Sajazir, Ruconest, or Kalbitor	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CINRYZE	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500 UNIT	85802022002120	Brand
RUCONEST	C1 ESTERASE INHIBITOR (RECOMBINANT) FOR IV INJ 2100 UNIT	85802022102130	Brand
FIRAZYR	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Brand

ICATIBANT ACETATE	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Generic
SAJAZIR	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Generic
SAJAZIR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
FIRAZYR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Brand
ICATIBANT ACETATE	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
KALBITOR	ECALLANTIDE INJ 10 MG/ML	85840030002020	Brand

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A, E]:

2.1 Diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 Normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze only)
- Patient is 12 years of age or older (applies to Kalbitor only) [D]
- Patient is 13 years of age or older (applies to Ruconest only) [5]
- Patient is 18 years of age or older (applies to Brand Firazyr, generic icatibant, and Sajazir only)

AND

6 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

AND

7 - Trial and failure or intolerance to generic icatibant (applies to brand Firazyr only):

Product Name:Cinryze [off-label], Brand Firazyr, Generic icatibant, Sajazir, Ruconest, or Kalbitor	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CINRYZE	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500 UNIT	85802022002120	Brand
RUCONEST	C1 ESTERASE INHIBITOR (RECOMBINANT) FOR IV INJ 2100 UNIT	85802022102130	Brand
FIRAZYR	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Brand
ICATIBANT ACETATE	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Generic
SAJAZIR	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Generic
SAJAZIR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
FIRAZYR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Brand
ICATIBANT ACETATE	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
KALBITOR	ECALLANTIDE INJ 10 MG/ML	85840030002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Not used in combination with other approved treatments for acute HAE attacks

Product Name:Berinert	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BERINERT	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ KIT 500 UNIT	85802022006420	Brand

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A, E]:

2.1 Diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 Normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to Ruconest

OR

5.2 One of the following [5]:

- Patient is 12 years of age or younger
- Documentation that patient has history of laryngeal attacks

AND

6 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name:Berinert	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BERINERT	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ KIT 500 UNIT	85802022006420	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Not used in combination with other approved treatments for acute HAE attacks

Product Name:Cinryze	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CINRYZE	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500 UNIT	85802022002120	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A]:

2.1 Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:

2.2.1 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 Normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For prophylaxis against HAE attacks [3]

AND

4 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

AND

5 - Patient is 6 years of age or older

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication or intolerance to one of the following:

- Orladeyo
- Haegarda
- Takhzyro

OR

6.2 Both of the following:

6.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

6.2.2 Patient demonstrates positive clinical response to therapy

AND

7 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name:Brand Firazyr	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
FIRAZYR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A]:

2.1 Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:

2.2.1 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 Normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - Patient is 18 years of age or older

AND

6 - Both of the following:

6.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic icatibant

AND

6.2 Submission of medical records confirming generic icatibant has not been effective AND justification/rationale provided explaining how Brand Firazyr is expected to provide benefit when generic icatibant has not been shown to be effective despite having the same active ingredient

AND

7 - One of the following:

7.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication or intolerance to all of the following:

7.1.1 Berinert

AND

7.1.2 Kalbitor

AND

7.1.3 One of the following:

7.1.3.1 Ruconest

OR

7.1.3.2 Documentation that patient has history of laryngeal attacks

OR

7.2 Both of the following:

7.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

7.2.2 Patient demonstrates positive clinical response to therapy

AND

8 - Prescribed by or in consultation with one of the following: [B]

- Immunologist

- Allergist

3 . Endnotes

A. HAE is a rare genetic disorder that can be broadly divided into two fundamental types: 1) HAE-C1INH (HAE Type 1 or Type 2), which presents with a deficiency of C1-INH; 2) HAE-n1-C1INH (previously referred to as HAE Type 3), a rare variant which presents with normal C1-INH levels. This condition is inherited in an autosomal dominant manner characterized by recurrent episodes of angioedema, without urticaria or pruritus, which most often affect the skin or mucosal tissues of the upper respiratory and gastrointestinal tracts. Diagnosis of Type 1 or Type 2 HAE requires laboratory testing to confirm low or abnormal levels of C1-inhibitor. HAE-n1-C1INH (previously referred to as HAE Type 3) presents a diagnostic challenge given the current lack of a validated biochemical test to confirm diagnosis. Per HAE guidelines, when a diagnosis of HAE-n1-CINH is suspected based on normal C1-INH levels, diagnosis should be confirmed by a known mutation associated with the disease or a positive family history of recurrent angioedema with a lack of efficacy to high-dose antihistamine therapy [10, 14].

B. Includes immunologist and allergist specialties to ensure the requirement for proper diagnosing and assessing the severity of the symptoms. In the pivotal Cinryze trial, criteria for participation of long term prophylaxis included patients 9 years and older with documented HAE (based on: a low C4 level plus low C1 inhibitor antigenic level/or low C1 inhibitor functional level OR a known HAE causing mutation) AND a history of at least two HAE attack per month. [1, 8] Berinert is approved for the treatment of acute attacks in patients who are 13 years and older. In the pivotal Berinert trial patients had laboratory-confirmed C1-inhibitor deficiency (type I or II HAE). [9]

C. Following treatment with nanofiltered C1 inhibitor concentrate (Cinryze) for an acute attack, the median time to response was 30 minutes in 82 patients with hereditary angioedema (median number of attacks per patient, 3; range, 1 to 57 attacks) in an open-label extension trial (median follow-up of 11 months). Additionally, 93% of attacks responded within 4 hr after C1 inhibitor concentrate treatment. [3]

D. Kalbitor carries a black box warning that states the following: "Anaphylaxis has been reported after administration of Kalbitor. Because of the risk of anaphylaxis, Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema (HAE). Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely. Do not administer Kalbitor to patients with known clinical hypersensitivity to Kalbitor." In 255 HAE patients treated with intravenous or subcutaneous Kalbitor in clinical studies, 10 patients (3.9%) experienced anaphylaxis. For the subgroup of 187 patients treated with subcutaneous Kalbitor, 5 patients (2.7%) experienced anaphylaxis. Symptoms associated with these reactions have included chest discomfort, flushing, pharyngeal edema, pruritus, rhinorrhea, sneezing, nasal congestion, throat irritation, urticaria, wheezing, and hypotension. These reactions occurred within the first hour after dosing. Other adverse reactions indicative of hypersensitivity reactions included the following: pruritus (5.1%), rash (3.1%), and urticaria (2.0%). Patients should be observed for an appropriate period of time after administration of Kalbitor, taking into account the time to

onset of anaphylaxis seen in clinical trials. In the Kalbitor HAE program, patients developed antibodies to ecallantide. Rates of seroconversion increased with exposure to ecallantide over time. Overall, 7.4% of patients seroconverted to anti-ecallantide antibodies. Neutralizing antibodies to ecallantide were determined in vitro to be present in 4.7% of patients. Anti-ecallantide and anti-Po pastoris IgE antibodies were also detected. While the long-term effects of antibodies to Kalbitor are not known, patients who seroconvert may be at a higher risk of a hypersensitivity reaction. The manufacturer developed a Risk Evaluation and Mitigation Strategy (REMS) program consisting of a Medication Guide and Communication Plan to notify healthcare professionals of the risk of anaphylaxis and the need to distinguish signs and symptoms of anaphylaxis and HAE attack as they may overlap. The presence of the black box warning necessitating administration by a healthcare professional; development of antibodies to ecallantide that may predispose patients to higher risks of hypersensitivity reactions; and the requirement for a REMS program offer compelling evidence to warrant the continued inclusion of an age criterion. [7]

E. When HAE is suspected based on the clinical presentation, appropriate testing includes measurement of the serum C4 level, C1INH antigenic level, and C1INH functional level. Low C4 plus low C1INH antigenic or functional levels are consistent with a diagnosis of HAE-C1INH [14, 15].

4 . References

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5 . Revision History

Date	Notes
1/16/2025	Custom guideline for Quartz Com mirrow Optum standard with no ch ange to criteria.

Prior Authorization Guideline

Guideline ID	GL-228871
Guideline Name	Hetlioz, Hetlioz LQ (tasimelteon) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Hetlioz (tasimelteon) capsule
Non-24-Hour Sleep-Wake Disorder (Non-24) Indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adults. **Smith-Magenis Syndrome (SMS)** Indicated for the treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older.
Drug Name: Hetlioz LQ (tasimelteon) suspension
Smith-Magenis Syndrome (SMS) Indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in pediatric patients 3 to 15 years of age.

2 . Criteria

Product Name:Brand Hetlioz capsule, generic tasimelteon capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand
TASIMELTEON	TASIMELTEON CAPSULE 20 MG	60250070000130	Generic

Approval Criteria

1 - Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome) [2, 5-6, A]

AND

2 - Patient is totally blind (has no light perception) [2-8, B]

AND

3 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name:Brand Hetlioz capsule, generic tasimelteon capsule

Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand
TASIMELTEON	TASIMELTEON CAPSULE 20 MG	60250070000130	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Brand Hetlioz capsule, generic tasimelteon capsule	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand
TASIMELTEON	TASIMELTEON CAPSULE 20 MG	60250070000130	Generic

Approval Criteria

1 - Diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 16 years of age or older

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)

AND

5 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name:Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ LQ	TASIMELTEON ORAL SUSP 4 MG/ML	60250070001820	Brand

Approval Criteria

1 - Diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 3 through 15 years of age

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name:Brand Hetlioz capsule, generic tasimelteon capsule, Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand
HETLIOZ LQ	TASIMELTEON ORAL SUSP 4 MG/ML	60250070001820	Brand
TASIMELTEON	TASIMELTEON CAPSULE 20 MG	60250070000130	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

Product Name:Hetlioz capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)

Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome) [2, 5-6, A]

AND

2 - Patient is totally blind (has no light perception) [2-8, B]

AND

3 - Submission of medical records (e.g., chart notes) confirming all of the following (Applies to Brand only):

- Patient has experienced intolerance (e.g., allergy to excipient) with generic tasimelteon
- Generic tasimelteon has not been effective
- Justification or rationale explaining how Brand Hetlioz capsule is expected to provide benefit when generic tasimelteon has not been shown to be effective despite having the same active ingredient

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name:Hetlioz capsule

Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 16 years of age or older

AND

3 - Submission of medical records (e.g., chart notes) confirming patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Submission of medical records (e.g., chart notes) confirming all of the following (Applies to Brand only):

- Patient has experienced intolerance (e.g., allergy to excipient) with generic tasimelteon
- Generic tasimelteon has not been effective
- Justification or rationale explaining how Brand Hetlioz capsule is expected to provide benefit when generic tasimelteon has not been shown to be effective despite having the same active ingredient

AND

5 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name:Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ LQ	TASIMELTEON ORAL SUSP 4 MG/ML	60250070001820	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 3 through 15 years of age

AND

3 - Submission of medical records (e.g., chart notes) confirming patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders

- Neurologist

3 . Endnotes

A. The International Classification of Sleep Disorders (an official publication of the American Academy of Sleep Medicine) defines non-24-hour sleep-wake disorder as a circadian rhythm sleep disorder characterized by complaints of insomnia or excessive sleepiness related to abnormal synchronization between the 24-hour light-dark cycle and the endogenous circadian rhythms of sleep and wake propensity, for a duration of 3 months. [2] Patients with non-24 experience a chronic steady pattern comprising 1- to 2-hour daily delays in sleep onset and wake times. As incremental phase delays in sleep occur, the complaint will consist of difficulty initiating sleep at night coupled with oversleeping into the daytime hours or inability to remain awake in the daytime. Therefore, over long periods of time, patients alternate between being symptomatic and asymptomatic, depending on the degree of synchrony between their internal biologic rhythm and the 24-hour world. [2] The condition is very rare in normally sighted people, but quite common in the totally blind who have no access to the entraining effects of the light-dark cycle. [3] Of the estimated 1.3 million legally blind individuals in the United States, approximately 130,000 have no light perception. Epidemiologic studies have found that as many as 70% of this totally blind sub-population suffer from non-24. [4] Non-24 is considered a chronic condition and markedly decreases the quality of life for patients. To varying extents, individuals with non-24 are unable to function in scheduled social activities or hold conventional jobs. [2, 4]

B. Hetlioz was approved on the basis of two pivotal, randomized, double-masked, placebo-controlled, multicenter, parallel-group studies in totally blind patients with non-24-hour sleep-wake disorder. [1, 7] The Safety and Efficacy of Tasimelteon (SET) Trial [1,7] was conducted in 84 totally blind patients with non-24, aged 21-84 years. Subjects received either Hetlioz 20 mg or placebo, one hour prior to bedtime, at the same time every night for up to 6 months. The Randomized-withdrawal study of the Efficacy and Safety of Tasimelteon to treat non-24 (RESET) Trial [1,8] was conducted in 20 entrained totally blind patients with non-24, aged 28-70 years. Subjects were treated for approximately 12 weeks with Hetlioz 20 mg one hour prior to bedtime, at the same time every night. Patients in whom the calculated time of peak melatonin level (melatonin acrophase) occurred at approximately the same time of day (in contrast to the expected daily delay) during the run-in phase were randomized to receive placebo or continue treatment with Hetlioz 20 mg for 8 weeks.

C. Given the wide range of available dosing regimens for melatonin, the variability in response time to treatment with tasimelteon and melatonin, and the need for consistent monitoring and evaluation of patients' sleep-related symptoms, tasimelteon must be prescribed by or in consultation with a specialist in sleep disorders. [3]

4 . References

1. Hetlioz Prescribing Information. Vanda Pharmaceuticals, Inc. Washington D.C. December 2020.
2. International Classification of Sleep Disorders. 3rd ed. Darien, IL: American academy of sleep medicine; 2014.
3. Sack RL, Auckley D, Auger RR, et al. Circadian rhythm sleep disorders: Part II, advanced sleep phase disorder, delayed sleep phase disorder, free-running disorder, and irregular sleep-wake rhythm. Sleep 2007;30(11):1484-1501.
4. Vanda Pharmaceuticals, Inc. About Non-24. Available at: http://www.non-24.com/about-non-24.php. Accessed September 27, 2017.
5. National Sleep Foundation. Non-24-hour Sleep Wake Disorder Facts and Prevalence. Available at: https://www.sleepfoundation.org/non-24-sleep-wake-disorder/treatment-care. May 13, 2022. Accessed June 16, 2022.
6. Circadian Sleep Disorders Network. Non-24-Hour Sleep-Wake Disorder Questions and Answers. Available at: http://www.circadiansleepdisorders.org/docs/N24-QandA.php. Accessed September 27, 2017.
7. Lockley SW, Dressman MA, Xiao C, et al. Tasimelteon treatment entrains the circadian clock and demonstrates a clinically meaningful benefit in totally blind individuals with non-24-hour circadian rhythms [Poster abstract no. FP26-6]. 95th Annual Meeting of the Endocrine Society; 15-18 Jun 2013; San Francisco, CA.
8. Lockley SW, Dressman MA, Xiao C, Licamele L, Polymeropoulos MH. RESET study demonstrates that tasimelteon maintains entrainment of melatonin and cortisol in totally blind individuals with non-24-hour circadian rhythms [Poster abstract no. SUN-137]. 95th Annual Meeting of the Endocrine Society; 15-18 Jun 2013; San Francisco, CA.
9. National Organization for Rare Disorders. Non-24-Hour Sleep-Wake Disorder Available at: https://rarediseases.org/rare-diseases/non-24-hour-sleep-wake-disorder/Accessed June 16, 2022.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228872
Guideline Name	High Cost, Low Value Non-Formulary Program
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:A Non-Preferred Non-Formulary or Excluded Medication* (Brand Absorica, Absorica LD, Brand Aczone, Brand Adapalene 0.1% pads, Anusol-HC suppository, Arazlo, Atopaderm, Azesco, Bensal HP, Cabtreo, generic chlorzoxazone, Coxanto, Brand Oxaprozin, Brand Diclofenac Epolamine, Brand Doryx, Brand Doryx MPC, generic doxepin cream, Epiceram, generic fenoprofen calcium, Flector, Fluovix, Folic-K, Genicin Vita-S, Brand Inderal XL, Innopran XL, Kamdoy, Kelarx, Licart, Brand Lidocaine-tetracaine cream, Brand Naprosyn, generic naproxen-esomeprazole, Brand Oracea, Ortho DF, Brand Pennsaid, Pliaglis, Pokonza, Pregenna, Prodigen, Promethazine VC syrup, Promethazine/codeine syrup, Brand Prudoxin, Rayos, Relafen DS, Sajazir, Sitavig, Sprix, Tivorbex, Tolsura, Brand Vimovo, Winlevi, Xerese, Xhance, Yosprala, Zipsor, Brand Zonalon, Zorvolex, ZT Lido, Brand Zyclara, Zyflo)	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ABSORICA	ISOTRETINOIN CAP 10 MG	90050013000110	Brand
ABSORICA	ISOTRETINOIN CAP 20 MG	90050013000120	Brand
ABSORICA	ISOTRETINOIN CAP 25 MG	90050013000125	Brand
ABSORICA	ISOTRETINOIN CAP 30 MG	90050013000130	Brand
ABSORICA	ISOTRETINOIN CAP 35 MG	90050013000135	Brand
ABSORICA	ISOTRETINOIN CAP 40 MG	90050013000140	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 8 MG	90050013100110	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 16 MG	90050013100115	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 24 MG	90050013100125	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 32 MG	90050013100135	Brand
SITAVIG	ACYCLOVIR BUCCAL TAB 50 MG	12405010000365	Brand
VIMOVO	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 375-20 MG	66109902440620	Brand
NAPROXEN/ESOMEPRAZOLE MAGNESIUM	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 375-20 MG	66109902440620	Generic
VIMOVO	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 500-20 MG	66109902440640	Brand
NAPROXEN/ESOMEPRAZOLE MAGNESIUM	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 500-20 MG	66109902440640	Generic
XERESE	ACYCLOVIR-HYDROCORTISONE CREAM 5-1%	90359902153720	Brand
ZIPSOR	DICLOFENAC POTASSIUM CAP 25 MG	66100007100120	Brand
ZYFLO	ZILEUTON TAB 600 MG	44504085000330	Brand
SPRIX	KETOROLAC TROMETHAMINE NASAL SPRAY 15.75 MG/SPRAY	66100037102090	Generic
RELAFEN DS	NABUMETONE TAB 1000 MG	66100055000340	Brand
ZORVOLEX	DICLOFENAC CAP 18 MG	66100007000120	Brand
ZORVOLEX	DICLOFENAC CAP 35 MG	66100007000130	Generic
TOLSURA	ITRACONAZOLE CAP 65 MG	11407035000113	Brand
INNOPRAN XL	PROPRANOLOL HCL SUSTAINED-RELEASE BEADS CAP ER 24HR 80 MG	33100040127020	Brand
INDERAL XL	PROPRANOLOL HCL SUSTAINED-RELEASE BEADS CAP ER 24HR 80 MG	33100040127020	Brand

INNOPRAN XL	PROPRANOLOL HCL SUSTAINED-RELEASE BEADS CAP ER 24HR 120 MG	33100040127030	Brand
INDERAL XL	PROPRANOLOL HCL SUSTAINED-RELEASE BEADS CAP ER 24HR 120 MG	33100040127030	Brand
RAYOS	PREDNISONE TAB DELAYED RELEASE 1 MG	22100045000610	Brand
RAYOS	PREDNISONE TAB DELAYED RELEASE 2 MG	22100045000620	Brand
RAYOS	PREDNISONE TAB DELAYED RELEASE 5 MG	22100045000630	Brand
PENNSAID	DICLOFENAC SODIUM SOLN 2%	90210030302030	Brand
FLECTOR	DICLOFENAC EPOLAMINE PATCH 1.3%	90210030205920	Generic
ZTLIDO	LIDOCAINE PATCH 1.8% (36 MG)	90850060005910	Brand
YOSPRALA	ASPIRIN-OMEPRAZOLE TAB DELAYED RELEASE 81-40 MG	85159902040620	Generic
YOSPRALA	ASPIRIN-OMEPRAZOLE TAB DELAYED RELEASE 325-40 MG	85159902040630	Generic
AZESCO	*PRENATAL VIT W/ FE GLUCONATE-FA TAB 13-1 MG***	78512020000320	Brand
DORYX	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 50 MG	04000020100610	Brand
DORYX	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 80 MG	04000020100624	Brand
DORYX	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 200 MG	04000020100650	Brand
ZYCLARA	IMIQUIMOD CREAM 3.75%	90773040003715	Brand
ATOPADERM	*DERMATOLOGICAL PRODUCTS MISC - CREAM**	90990000003700	Brand
BENSAL HP	SALICYLIC ACID OINT 3%	90750030004210	Brand
CHLORZOXAZONE	CHLORZOXAZONE TAB 250 MG	75100040000305	Generic
CHLORZOXAZONE	CHLORZOXAZONE TAB 375 MG	75100040000307	Generic
CHLORZOXAZONE	CHLORZOXAZONE TAB 500 MG	75100040000310	Generic
CHLORZOXAZONE	CHLORZOXAZONE TAB 750 MG	75100040000320	Generic
EPICERAM	*DERMATOLOGICAL PRODUCTS MISC - EMULSION**	90990000001600	Brand
FENOPROFEN CALCIUM	FENOPROFEN CALCIUM CAP 200 MG	66100010100105	Generic
FENOPROFEN CALCIUM	FENOPROFEN CALCIUM CAP 400 MG	66100010100120	Generic

FENOPROFEN CALCIUM	FENOPROFEN CALCIUM TAB 600 MG	66100010100305	Generic
FLUOVIX	*FLUOCINONIDE CREAM 0.1% & SILICONE TAPE THERAPY PACK***	9055990242B120	Brand
FLUOVIX PLUS	*FLUOCINONIDE CREAM 0.1% & SILICONE TAPE THERAPY PACK***	9055990242B120	Brand
FOLIC-K	*B-COMPLEX W/ E & FOLIC ACID CAP 1 MG***	78133400000120	Brand
GENICIN VITA-S	*B-COMPLEX W/ C & FOLIC ACID TAB 1 MG***	78133000000330	Brand
KAMDOY	*DERMATOLOGICAL PRODUCTS MISC - EMULSION**	90990000001600	Brand
KELARX	*SCAR TREATMENT PRODUCTS - GEL**	90930000004000	Brand
LIDOCAINE AND TETRACAINE CREAM	LIDOCAINE-TETRACAINE CREAM 7-7%	90859902843730	Generic
LIDOCAINE/TETRACAINE	LIDOCAINE-TETRACAINE CREAM 7-7%	90859902843730	Generic
PLIAGLIS	LIDOCAINE-TETRACAINE CREAM 7-7%	90859902843730	Generic
NAPROSYN	NAPROXEN TAB 500 MG	66100060000315	Brand
NAPROSYN	NAPROXEN SUSP 125 MG/5ML	66100060001805	Brand
ORTHO DF	FOLIC ACID-CHOLECALCIFEROL CAP 1 MG-3775 UNIT	82991502400120	Brand
PREGENNA	*PRENAT VIT W/FE BISGLYC CHELATE-FA TAB 20-1MG (1.7MG DFE)**	78512046000315	Brand
PRODIGEN	*PROBIOTIC PRODUCT - CAP**	47300025000100	Brand
TIVORBEX	INDOMETHACIN CAP 20 MG	66100030000104	Generic
ZONALON	DOXEPIN HCL CREAM 5%	90220015103710	Brand
DOXEPIN HYDROCHLORIDE	DOXEPIN HCL CREAM 5%	90220015103710	Generic
PRUDOXIN	DOXEPIN HCL CREAM 5%	90220015103710	Brand
XHANCE	FLUTICASONE PROPIONATE NASAL EXHALER SUSP 93 MCG/ACT	4220003230G720	Brand
DICLOFENAC EPOLAMINE	DICLOFENAC EPOLAMINE PATCH 1.3%	90210030205920	Generic
ZYCLARA PUMP	IMIQUIMOD CREAM 2.5%	90773040003710	Brand
ZYCLARA PUMP	IMIQUIMOD CREAM 3.75%	90773040003715	Brand
FLECTOR	DICLOFENAC EPOLAMINE PATCH 1.3%	90210030205920	Generic
non-preferred			

DORYX MPC	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 60 MG	04000020100615	Brand
DORYX MPC	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 120 MG	04000020100635	Brand
ADAPALENE	ADAPALENE PADS 0.1%	90050003004310	Brand
POKONZA	POTASSIUM CHLORIDE POWDER PACKET 10 MEQ	79700030003005	Brand
WINLEVI	CLASCOTERONE CREAM 1%	90050011003720	Brand
SAJAZIR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
ARAZLO	TAZAROTENE (ACNE) LOTION 0.045%	90050027004120	Brand
COXANTO	OXAPROZIN CAP 300 MG	66100065000120	Generic
OXAPROZIN	OXAPROZIN CAP 300 MG	66100065000120	Generic
CABTREO	ADAPALENE-BENZOYL PEROXIDE-CLINDAMYCIN GEL 0.15-3.1-1.2%	90059903024018	Brand
PROMETHAZINE HYDROCHLORIDE PLAIN	PROMETHAZINE HCL ORAL SOLN 6.25 MG/5ML	41400020102060	Generic
PROMETHAZINE HYDROCHLORIDE	PROMETHAZINE HCL ORAL SOLN 6.25 MG/5ML	41400020102060	Generic
PROMETHAZINE VC	PROMETHAZINE & PHENYLEPHRINE SYRUP 6.25-5 MG/5ML	43993002701210	Generic
LICART	DICLOFENAC EPOLAMINE PATCH 24HR 1.3%	90210030208520	Brand
ORACEA	DOXYCYCLINE (ROSACEA) CAP DELAYED RELEASE 40 MG	90060025006520	Brand
ACZONE	DAPSONE GEL 5%	90051015004020	Brand
ACZONE	DAPSONE GEL 7.5%	90051015004030	Brand
ANUSOL-HC	HYDROCORTISONE ACETATE SUPPOS 25 MG	89100010105230	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming request is for an FDA-approved indication

AND

2 - Submission of medical records (e.g., chart notes) (document drug, duration, dose and date of use) confirming history of use of ALL available formulary alternative(s) and over-the-counter (OTC) equivalents*^ (if request is for a combination product, member must have documentation indicating concurrent use of separate agents)

AND

3 - Both of the following:

3.1 Documentation provided stating the formulary alternative(s) and over-the-counter (OTC) equivalents*^ has/have not been effective

AND

3.2 Justification/rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternative product(s) and over-the-counter (OTC) equivalents*^ has/have not been shown to be effective despite having the same active ingredient and/or same mechanism of action

Notes	*See table in background section for a list of the Non-Formulary or Ex cluded Medications and their preferred formulary alternatives. Please double check plan formulary for coverage. For off-label use, do not re view against the off-label administration guideline. Deny per guideline criteria. ^OTC equivalents refers to any covered or non-covered OTC equivalent product.

2 . Background

Benefit/Coverage/Program Information

Non-Formulary or Excluded Medications and their *^Formulary Alternatives and OTC equivalents

Non-Formulary or Excluded Medication	*^Formulary Alternatives and OTC equivalents
Brand Absorica, Absorica LD	Amnesteem Claravis

	Isotretinoin Myorisan Zenatane
Brand Aczone	Amzeeq Cleocin-T Clindacin Clindamycin Klaron Sodium sulfacetamide lotion
Adapalene 0.1% Pads, Arazlo	Aklief Generic adapalene (cream or gel) Generic tretinoin containing products Generic clindamycin containing products Erythromycin/benzoyl peroxide Neuac Tazarotene cream Twyneo
Anusol-HC suppository	Analpram-HC cream Hydrocortisone acetate/pramoxine Proctofoam HC Anusol-HC cream Hydrocortisone Procto-med HC Proctosol HC Proctozone-HC
Atopaderm	Desonide Hydrocortisone Aquaphor

	Eucerin Lubriderm
Azesco	PrePLUS prenatal vitamin CVS prenatal multivitamin Thorne Basic Prenatal Vitamin Aminatal Plus Active OB Atabex OB Tab 29-1mg
Bensal HP	Podofilox Ciclopirox Gold Bond Ultimate Psoriasis Cerave SA moisturizing cream for rough & bumpy skin Q+A Salicylic Acid Smoothing Lotion
Cabtreo	Adapalene Cleocin Clindamycin phosphate/benzoyl peroxide Onexton Clindamycin phosphate/tretinoin Clinoin Erythromycin/benzoyl peroxide Neuac
Coxanto, Brand Oxaprozin	Celecoxib Daypro Diclofenac (oral) Naprosyn Naproxen Flurbiprofen

	Ketoprofen Meloxicam Nabumetone Piroxicam Sulindac
Generic chlorzoxazone	Methocarbamol Cyclobenzaprine tablet Metaxalone Orphenadrine ER Tizanidine
Generic doxepin 5% cream, Brand Prudoxin, Brand Zonalon	Betamethasone dipropionate cream Tacrolimus 0.1% ointment Generic hydrocortisone 1% cream
Brand Doryx, Brand Doryx MPC	Generic doxycycline delayed release Generic doxycycline monohydrate Brand Vibramycin
Epiceram	Aquaphor Eucerin Lubriderm
Generic fenoprofen calcium, Brand Naprosyn	Celecoxib Ibuprofen (tablet/suspension) Diclofenac Etodolac Meloxicam
Flector, Brand Diclofenac epolamine, Licart	Generic topical diclofenac gel Celecoxib Ibuprofen (oral)

	Diclofenac (oral) Etodolac Meloxicam
Fluovix, Fluvovix Plus	Generic fluocinonide cream 0.1%, Generic clobetasol propionate 0.05% cream Generic Halobetasol Propionate 0.05% Cream
Genicin Vita-S	Generic B-Complex with C and Folic Acid Nature's Bounty Super B-complex with Folic Acid Plus Vitamin C Tablets DISCSunmark Vitamin B Complex with Vitamin C Tablets Thorne Ferrasorb
Inderal XL/Innopran XL	Propranolol extended release Nadolol Pindolol Timolol maleate tablets
Kamdoy	Aspercreme Pain Relief Cream with Lidocaine Equate Max Strength Lidocaine Pain Relieving Cream Blue-Emu Lidocaine Pain Relief Cream OTC Lidocaine Cream
Kelarx	Scaraway HF Physician Formulated Silicone Scar Gel Kelo-Cote Scar Gel
Brand Lidocaine-tetracaine cream, Pliaglis	Lidocaine-prilocaine cream Lidocaine cream Lidtopic Max Glydo

Brand Oracea	Azelaic acid Doxycycline Finacea Ivermectin Metrocream Metrolotion Metronidazole cream Minocycline Soolantra Zilixi
Ortho DF	Vitamin D3 (OTC) Folic Acid Beeline Vitality Tablets NatureMade Vitamin D/ Folic Acid
Pennsaid	Diclofenac sodium solution 1.5% Diclofenac sodium solution 2% Celecoxib Etodolac Ketoprofen Naproxen Meloxicam Nabumetone Sulindac
Pokonza	Klor-Con Potassium chloride Potassium chloride (CR, ER)
Pregenna	Atabex OB Tab 29-1mg PrePLUS prenatal vitamin

	CVS prenatal multivitamin Thorne Basic Prenatal Vitamin Aminatal Plus Active OB Vinate II
Prodigen	Alflorex Bio-Kult Visbiome Optibac Probiotics Every Day
Promethazine VC/codeine syrup; promethazine VC syrup	Brompheniramine / dextromethorphan / pseudoephedrine syrup Guaifenesin / pseudoephedrine syrup Guaifenesin / phenylephrine syrup
Relafen DS, Zipsor, Zorvolex	Diclofenac Etodolac Ketoprofen Naproxen Meloxicam Nabumetone Piroxicam Sulindac
Rayos	Medrol Methylprednisolone Pediapred Prednisolone Prednisone
Sajazir	Berinert Ruconest

	Icatibant acetate	
Sitavig	Acyclovir 5% cream Penciclovir 1% cream Acyclovir oral Valacyclovir oral	
Sprix	Brand Ketorolac nasal spray Generic ketorolac oral tablets Celecoxib Diclofenac Naprosyn Etodolac Ibuprofen Ketoprofen Sulindac Piroxicam Nabumetone	
Tivorbex	Celecoxib Ibuprofen Indomethacin Colcrys Diclofenac Etodolac Meloxicam	
Tolsura	Itraconazole 100 mg capsules Sporanox Ketoconazole	
	NSAID	**ANTI-ULCER AGENT**

<table>
<tr><td rowspan="9">Brand Vimovo, generic naproxen/esomeprazole</td><td>Diclofenac</td><td>Esomeprazole</td></tr>
<tr><td>Indomethacin</td><td>Lansoprazole</td></tr>
<tr><td>Ketoprofen</td><td>Omeprazole</td></tr>
<tr><td>Naproxen</td><td>Rabeprazole</td></tr>
<tr><td>Meloxicam</td><td>Pantoprazole</td></tr>
<tr><td>Nabumetone</td><td></td></tr>
<tr><td>Piroxicam</td><td></td></tr>
<tr><td>Sulindac</td><td></td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>Winlevi</td><td colspan="2">Generic adapalene (cream, gel, lotion)
Generic tretinoin containing products
Generic tazarotene cream
Generic single-agent clindamycin product
Generic Dapsone gel</td></tr>
<tr><td>Xerese</td><td colspan="2">Acyclovir 5% Cream
Acyclovir (oral)
Famciclovir (oral)
Hydrocortisone 1% Cream
Penciclovir cream
Valacyclovir (oral)</td></tr>
<tr><td>Xhance</td><td colspan="2">Generic mometasone nasal spray
Generic fluticasone nasal spray
OTC budesonide nasal spray
Omnaris nasal spray
Qnasl nasal spray
OTC triamcinolone nasal spray
Zetonna nasal spray</td></tr>
</table>

Yosprala	Aspirin	Omeprazole
		Esomeprazole
		Pantoprazole
		Lansoprazole
		Rabeprazole
ZTlido	Fanatrex Fusepaq Gralise Horizant Lidocaine 5% patch Gabapentin Pregabalin	
Brand Zyclara	Imiquimod 5% cream Diclofenac 3% gel Fluorouracil 2% solution Fluorouracil 5% cream Carac Efudex Tolak Condylox Podofilox Klisyri	
Zyflo	Accolate Montelukast Zafirlukast	

3 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228657
Guideline Name	High-Cost Brand with Generics Program
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Drugs included on the High Cost Brand with Generics List for which a Drug-Specific Prior Authorization Guideline is Unavailable*	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

AND

1.1.3 Requested drug will be used at a dose which is within FDA recommendations

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - All of the following:

2.1 Patient has experienced intolerance (e.g., allergy to excipient) with the generic of the requested Brand

AND

2.2 If the requested drug is a Brand fixed-dose combination product, patient has experienced intolerance (e.g., allergy to excipient) with the individual generics in the combination product separately

AND

2.3 Submission of records (e.g., chart notes) confirming why the Brand is expected to provide benefit when the generic product has not been shown to be effective despite having the same active ingredient

AND

3 - One of the following:**

3.1 Patient has tried and failed at least 2 additional lower tier alternatives within the same therapeutic class. If only 1 lower tier alternative within the therapeutic class is available, the patient must have tried the lower tier alternative within the therapeutic class AND 1 additional lower tier alternative. If there are no lower tier alternatives within the same therapeutic class, the patient must have failed or had contraindication or intolerance to 2 lower tier alternatives

OR

3.2 No lower tier alternative is available to treat the patient's condition

Notes	*Drug should be reviewed using the drug-specific Prior Authorization guideline if available. If no drug-specific Prior Authorization guideline is available, proceed with the criteria above. **Please use the ORx Commercial grid to identify covered formulary generic alternatives for the requested target drug

Prior Authorization Guideline

Guideline ID	GL-228436
Guideline Name	High-Cost Generics Program
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Drugs included on the High Cost Generics List for which a Drug-Specific Prior Authorization Guideline is Unavailable*	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

AND

1.1.3 Requested drug will be used at a dose which is within FDA recommendations

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - One of the following:**

2.1 If the requested drug has a formulary generic alternative with the same active ingredient, both of the following:

2.1.1 Patient has experienced intolerance (e.g., allergy to excipient) with a formulary generic alternative that has the same active ingredient

AND

2.1.2 Patient has tried and failed at least 2 additional formulary generic alternatives within the same therapeutic class. If only 1 formulary generic alternative within the therapeutic class is available, the patient must have tried the formulary generic alternative within the therapeutic class AND 1 additional formulary generic alternative. If there are no formulary generic alternatives within the same therapeutic class, the patient must have failed or had contraindication or intolerance to 2 formulary generic alternatives

OR

2.2 If formulary generic alternatives are available and do not meet above scenario, patient has tried and failed, or has contraindication or intolerance to at least 3 formulary generic alternatives. If only 1 or only 2 alternatives are available, the patient must have failed or had contraindications or intolerance to all available formulary generic alternatives

AND

3 - Submission of medical records (e.g., chart notes) confirming why the requested drug is expected to provide benefit when the formulary generic alternative(s) has not shown to be effective

Notes	*Drug should be reviewed using the drug-specific Prior Authorization guideline, if available. If no drug-specific Prior Authorization guideline is available, proceed with the criteria above. **Please use the ORx Commercial grid to identify covered formulary generic alternatives for the requested target drug

Prior Authorization Guideline

Guideline ID	GL-228660
Guideline Name	Horizant (gabapentin enacarbil)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Horizant (gabapentin enacarbil)
Restless Legs Syndrome (RLS) Indicated for the treatment of moderate-to-severe primary restless legs syndrome (RLS) in adults. Horizant is not recommended for patients who are required to sleep during the daytime and remain awake at night. **Postherpetic Neuralgia (PHN)** Indicated for the management of postherpetic neuralgia (PHN) in adults.

2 . Criteria

Product Name:Horizant	
Diagnosis	Restless Legs Syndrome (RLS)
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HORIZANT	GABAPENTIN ENACARBIL TAB CR 300 MG	62560030200420	Brand
HORIZANT	GABAPENTIN ENACARBIL TAB CR 600 MG	62560030200430	Brand

Approval Criteria

1 - Diagnosis of moderate-to-severe primary restless legs syndrome (RLS)

Product Name:Horizant	
Diagnosis	Restless Legs Syndrome (RLS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HORIZANT	GABAPENTIN ENACARBIL TAB CR 300 MG	62560030200420	Brand
HORIZANT	GABAPENTIN ENACARBIL TAB CR 600 MG	62560030200430	Brand

Approval Criteria

1 - Patient has experienced an improvement in RLS disease symptoms (e.g., decrease in symptom onset or severity, improved sleep, or decrease in symptom intensity)

Product Name:Horizant	
Diagnosis	Postherpetic Neuralgia (PHN)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HORIZANT	GABAPENTIN ENACARBIL TAB CR 300 MG	62560030200420	Brand
HORIZANT	GABAPENTIN ENACARBIL TAB CR 600 MG	62560030200430	Brand

Approval Criteria

1 - Diagnosis of postherpetic neuralgia (PHN)

AND

2 - One of the following [A]:

2.1 Patient has tried and had an inadequate response to a dose of at least 1,800 mg of generic gabapentin

OR

2.2 History of intolerance to generic gabapentin

Product Name:Horizant	
Diagnosis	Postherpetic Neuralgia (PHN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HORIZANT	GABAPENTIN ENACARBIL TAB CR 300 MG	62560030200420	Brand
HORIZANT	GABAPENTIN ENACARBIL TAB CR 600 MG	62560030200430	Brand
HORIZANT	GABAPENTIN ENACARBIL TAB ER 300 MG	62560030200420	Brand
HORIZANT	GABAPENTIN ENACARBIL TAB ER 600 MG	62560030200430	Brand

Approval Criteria

1 - Patient has experienced an improvement in PHN disease symptoms (e.g., decrease in pain severity)

3 . Endnotes

A. While Horizant (gabapentin enacarbil) may improve patient convenience (twice daily rather than three times daily dosing), generic gabapentin is a more well-established, cost-effective therapy for PHN. The use of Horizant (gabapentin enacarbil) should be reserved for patients who have experienced treatment failure or intolerance to generic gabapentin. [3, 4]

4 . References

1. Horizant Prescribing Information. Arbor Pharmaceuticals, LLC. Atlanta, GA. April 2020.
2. Silber MH, Buchfuhrer MJ, Earley CJ, Koo BB, Manconi M, Winkelman JW; Scientific and Medical Advisory Board of the Restless Legs Syndrome Foundation. The Management of Restless Legs Syndrome: An Updated Algorithm. Mayo Clin Proc. 2021 Jul;96(7):1921-1937. doi: 10.1016/j.mayocp.2020.12.026.
3. Attal N, Cruccu G, Baron R, et al. EFNS guidelines on the pharmacological treatment of neuropathic pain: 2010 revision. Eur J of Neurol. 2010 Sep;17(9):1113-e88.
4. Johnson RW and Rice AS. Clinical Practice. Postherpetic neuralgia. N Engl J Med. 2014 Oct 16;371(16):1526-33.

Prior Authorization Guideline

Guideline ID	GL-229093
Guideline Name	Human Chorionic Gonadotropin (hCG)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/7/2025

1 . Indications

Drug Name: Novarel (chorionic gonadotropin), Pregnyl (chorionic gonadotropin)
Ovulation Induction (OI) Indicated for the induction of ovulation (OI) and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menotropins. **Prepubertal Cryptorchidism** Indicated for prepubertal cryptorchidism not due to anatomic obstruction. In general, hCG is thought to induce testicular descent in situations when descent would have occurred at puberty. hCG thus may help to predict whether or not orchiopexy will be needed in the future. Although, in some cases, descent following hCG administration is permanent, in most cases the response is temporary. Therapy is usually instituted between the ages of 4 and 9. **Hypogonadotropic Hypogonadism** Indicated for the treatment of selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males. **Off Label Uses: Infertile women undergoing Assisted Reproductive Technologies (ART)** Used for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated

with follicle-stimulating hormones (FSH) as part of an assisted reproductive technology (ART) program such as in vitro fertilization and embryo transfer. [3]

Drug Name: Ovidrel (chorionic gonadotropin) PreFilled Syringe

Infertile women undergoing Assisted Reproductive Technologies (ART) Indicated for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle-stimulating hormones (FSH) as part of an assisted reproductive technology (ART) program such as in vitro fertilization and embryo transfer.

Ovulation Induction (OI) Indicated for the induction of ovulation (OI) and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.

2 . Criteria

Product Name:Pregnyl*^	
Diagnosis	Ovulation Induction [4, 6]
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PREGNYL W/DILUENT BENZYL ALCOHOL/NACL	CHORIONIC GONADOTROPIN FOR INJ 10000 UNIT	30062020002140	Generic

Approval Criteria

1 - Diagnosis of anovulatory infertility

AND

2 - Infertility is not due to primary ovarian failure

AND

3 - For induction of ovulation

AND

4 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity. ^If patient meets c riteria above, please approve Pregnyl at GPI list “XXPAHCGORX”.

Product Name:Pregnyl* ^	
Diagnosis	Controlled Ovarian Hyperstimulation
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PREGNYL W/DILUENT BENZYL ALCOHOL/NACL	CHORIONIC GONADOTROPIN FOR INJ 10000 UNIT	30062020002140	Generic

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (controlled ovarian hyperstimulation)

AND

3 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)	
Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity. ^If patient meets c riteria above, please approve Pregnyl at GPI list “XXPAHCGORX”.

Product Name:Pregnyl	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PREGNYL W/DILUENT BENZYL ALCOHOL/NACL	CHORIONIC GONADOTROPIN FOR INJ 10000 UNIT	30062020002140	Generic

Approval Criteria

1 - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction [A]

Product Name:Pregnyl	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PREGNYL W/DILUENT BENZYL ALCOHOL/NACL	CHORIONIC GONADOTROPIN FOR INJ 10000 UNIT	30062020002140	Generic

Approval Criteria

1 - Diagnosis of male hypogonadism secondary to pituitary deficiency

AND

2 - Low testosterone (below normal reference level provided by the physician's laboratory)

AND

3 - One of the following:

- Low LH (below normal reference level provided by the physician's laboratory)
- Low FSH (below normal reference level provided by the physician's laboratory)

Product Name:Pregnyl	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PREGNYL W/DILUENT BENZYL ALCOHOL/NACL	CHORIONIC GONADOTROPIN FOR INJ 10000 UNIT	30062020002140	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

Product Name:Generic chorionic gonadotropin*^, Novarel*^, Ovidrel*^	
Diagnosis	Ovulation Induction [4, 6]
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHORIONIC GONADOTROPIN	CHORIONIC GONADOTROPIN FOR INJ 10000 UNIT	30062020002140	Generic
NOVAREL	CHORIONIC GONADOTROPIN FOR IM INJ 5000 UNIT	30062020002130	Brand
OVIDREL	CHORIOGONADOTROPIN ALFA INJ 250 MCG/0.5ML	3006202205E520	Brand

Approval Criteria

1 - Diagnosis of anovulatory infertility

AND

2 - Infertility is not due to primary ovarian failure

AND

3 - For induction of ovulation

AND

4 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)

Notes	*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity. ^If patient meets criteria above, please approve Generic chorionic gonadotropin, Novarel and Ovidrel at GPI list “XXPAHCGORX”.

Product Name:Generic chorionic gonadotropin*^, Novarel*^, Ovidrel*^	
Diagnosis	Controlled Ovarian Hyperstimulation
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

CHORIONIC GONADOTROPIN	CHORIONIC GONADOTROPIN FOR INJ 10000 UNIT	30062020002140	Generic
NOVAREL	CHORIONIC GONADOTROPIN FOR IM INJ 5000 UNIT	30062020002130	Brand
OVIDREL	CHORIOGONADOTROPIN ALFA INJ 250 MCG/0.5ML	3006202205E520	Brand

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (controlled ovarian hyperstimulation)

AND

3 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity. ^If patient meets c riteria above, please approve Generic chorionic gonadotropin, Novarel and Ovidrel at GPI list “XXPAHCGORX”.

Product Name:Generic chorionic gonadotropin, Novarel, Ovidrel	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHORIONIC GONADOTROPIN	CHORIONIC GONADOTROPIN FOR INJ 10000 UNIT	30062020002140	Generic
NOVAREL	CHORIONIC GONADOTROPIN FOR IM INJ 5000 UNIT	30062020002130	Brand
OVIDREL	CHORIOGONADOTROPIN ALFA INJ 250 MCG/0.5ML	3006202205E520	Brand

Approval Criteria

1 - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction [A]

Product Name:Generic chorionic gonadotropin, Novarel, Ovidrel	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHORIONIC GONADOTROPIN	CHORIONIC GONADOTROPIN FOR INJ 10000 UNIT	30062020002140	Generic
NOVAREL	CHORIONIC GONADOTROPIN FOR IM INJ 5000 UNIT	30062020002130	Brand
OVIDREL	CHORIOGONADOTROPIN ALFA INJ 250 MCG/0.5ML	3006202205E520	Brand

Approval Criteria

1 - Diagnosis of male hypogonadism secondary to pituitary deficiency

AND

2 - Low testosterone (below normal reference level provided by the physician's laboratory)

AND

3 - One of the following:

- Low LH (below normal reference level provided by the physician's laboratory)
- Low FSH (below normal reference level provided by the physician's laboratory)

Product Name:Generic chorionic gonadotropin, Novarel, Ovidrel	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHORIONIC GONADOTROPIN	CHORIONIC GONADOTROPIN FOR INJ 10000 UNIT	30062020002140	Generic
NOVAREL	CHORIONIC GONADOTROPIN FOR IM INJ 5000 UNIT	30062020002130	Brand
OVIDREL	CHORIOGONADOTROPIN ALFA INJ 250 MCG/0.5ML	3006202205E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

3 . Endnotes

A. In general, hCG is thought to induce testicular descent in situations when descent would have occurred at puberty. hCG thus may help predict whether or not orchiopexy (operation to bring an undescended testicle into the scrotum) will be needed in the future. Although, in some cases, descent following hCG administration is permanent, in most cases, the response is temporary. Therapy is usually initiated between the ages of 4 and 9. [1, 2, 4]

4 . References

1. Novarel prescribing information. Ferring Pharmaceuticals Inc. Parsippany, NJ. June 2023.
2. Pregnyl prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. March 2023.
3. Ovidrel prescribing information. EMD Serono, Inc. Rockland, MA. December 2023.
4. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed August 9, 2021.
5. Petak SM, Nankin HR, Spark RF, Swerdloff RS, Rodriguez-Rigau LJ. American Association of Clinical Endocrinologists Medical Guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients – 2002 update. Endocr Pract. 2002;8:440-456.

6. The Practice Committee of the American Society for Reproductive Medicine. Use of exogenous gonadotropins in anovulatory women: a technical bulletin. Fertil Steril. 2008;90:S7-12.

5 . Revision History

Date	Notes
1/7/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228662
Guideline Name	Hydroxyprogesterone caproate injection products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Hydroxyprogesterone caproate injection (for non-pregnant women)
Amenorrhea Indicated in non-pregnant women for the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer. **Production of secretory endometrium and desquamation** Indicated in non-pregnant women for the production of secretory endometrium and desquamation. **Adenocarcinoma of uterine corpus** Indicated in non-pregnant women for the treatment of advanced (Stage III or IV) adenocarcinoma of the uterine corpus. **Test for endogenous estrogen production** Indicated as a test for endogenous estrogen production in nonpregnant women.

2 . Criteria

Product Name:Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Amenorrhea, Abnormal uterine bleeding
Approval Length	4 Month [B]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYDROXYPROGESTERONE CAPROATE	HYDROXYPROGESTERONE CAPROATE IM IN OIL 1.25 GM/5ML	21404007202020	Generic

Approval Criteria

1 - Diagnosis of one of the following:

- Primary or secondary amenorrhea
- Abnormal uterine bleeding

AND

2 - Amenorrhea or abnormal uterine bleeding is due to hormonal imbalance in the absence of organic pathology (e.g., submucous fibroids or uterine cancer)

AND

3 - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s generic.

Product Name:Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Production of secretory endometrium and desquamation
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

HYDROXYPROGESTERONE CAPROATE	HYDROXYPROGESTERONE CAPROATE IM IN OIL 1.25 GM/5ML	21404007202020	Generic

Approval Criteria

1 - Used for production of secretory endometrium and desquamation

AND

2 - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s generic.

Product Name:Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Adenocarcinoma of uterine corpus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYDROXYPROGESTERONE CAPROATE	HYDROXYPROGESTERONE CAPROATE IM IN OIL 1.25 GM/5ML	21404007202020	Generic

Approval Criteria

1 - Diagnosis of Stage III or IV adenocarcinoma of the uterine corpus

AND

2 - Patient is not pregnant

AND

3 - Prescribed by or in consultation with an oncologist

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s generic.

Product Name:Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Adenocarcinoma of uterine corpus
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYDROXYPROGESTERONE CAPROATE	HYDROXYPROGESTERONE CAPROATE IM IN OIL 1.25 GM/5ML	21404007202020	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s generic.

Product Name:Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Test for endogenous estrogen production
Approval Length	2 Month [C]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYDROXYPROGESTERONE CAPROATE	HYDROXYPROGESTERONE CAPROATE IM IN OIL 1.25 GM/5ML	21404007202020	Generic

Approval Criteria **1** - Used for the testing of endogenous estrogen production **AND** **2** - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s generic.

3 . Definitions

Definition	Description
Singleton spontaneous preterm birth	Delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes. [1]

4 . Endnotes

A. Pregnant women with a history of preterm birth may benefit from initiating Makena therapy later than the FDA-recommended initiation period (between 16 weeks, 0 days and 20 weeks, 6 days gestation). There are no significant safety concerns with late initiation of therapy. Available evidence suggests it would be reasonable to allow initiation as late as 26 weeks, 6 days. [1-5]
B. Hydroxyprogesterone caproate injection (for non-pregnant women) for amenorrhea can be given as a one-time dosage or as cyclic therapy as part of a 28-day cycle, with each cycle repeated every 4 weeks and stopped after 4 cycles. [6]
C. Hydroxyprogesterone caproate injection (for non-pregnant women) for estrogen testing can be started at any time, with a repeat dose given 4 weeks after the first injection for confirmation. Therapy should be stopped after the second injection. [6]

5 . References

1. ACOG Committee Opinion number. Use of progesterone to reduce preterm birth. Obstet Gynecol. 2008 Oct;112(4):963-5.
2. Per clinical consult with women's health specialist. May 9, 2011.
3. How HY, Barton JR, Istwan NB, et al. Prophylaxis with 17 alpha-hydroxyprogesterone caproate for prevention of recurrent preterm delivery: does gestational age at initiation of treatment matter? Am J Obstet Gynecol. 2007;197(3):260.e1-4.
4. González-Quintero VH, Istwan NB, Rhea DJ, et al. Gestational age at initiation of 17-hydroxyprogesterone caproate (17P) and recurrent preterm delivery. J Matern Fetal Neonatal Med. 2007;20(3):249-52.
5. The choice of progestogen for the prevention of preterm birth in women with singleton pregnancy and prior preterm birth. Am J Obstet Gynecol. 2017;216(3):B11-B13. doi:10.1016/j.ajog.2017.01.022
6. Hydroxyprogesterone caproate injection Prescribing Information. AuroMedics Pharma LLC. Windsor, NJ. June 2022.
7. Prediction and prevention of spontaneous preterm birth. ACOG Practice Bulletin No. 234. American College of Obstetricians and Gynecologists. Obstet Gynecol 2021;138:e65–90.

Ibrance (palbociclib)

Prior Authorization Guideline

Guideline ID	GL-228874
Guideline Name	Ibrance (palbociclib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ibrance (palbociclib)
Breast Cancer Indicated for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with: (1) an aromatase inhibitor as initial endocrine based therapy, or (2) fulvestrant in patients with disease progression following endocrine therapy.

2 . Criteria

Product Name:Ibrance	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IBRANCE	PALBOCICLIB CAP 75 MG	21531060000120	Brand
IBRANCE	PALBOCICLIB CAP 100 MG	21531060000130	Brand
IBRANCE	PALBOCICLIB CAP 125 MG	21531060000140	Brand
IBRANCE	PALBOCICLIB TAB 75 MG	21531060000320	Brand
IBRANCE	PALBOCICLIB TAB 100 MG	21531060000330	Brand
IBRANCE	PALBOCICLIB TAB 125 MG	21531060000340	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kisqali (ribociclib)
- Verzenio (abemaciclib)

OR

2.2 For continuation of prior therapy

Product Name:Ibrance	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IBRANCE	PALBOCICLIB CAP 75 MG	21531060000120	Brand
IBRANCE	PALBOCICLIB CAP 100 MG	21531060000130	Brand

IBRANCE	PALBOCICLIB CAP 125 MG	21531060000140	Brand
IBRANCE	PALBOCICLIB TAB 75 MG	21531060000320	Brand
IBRANCE	PALBOCICLIB TAB 100 MG	21531060000330	Brand
IBRANCE	PALBOCICLIB TAB 125 MG	21531060000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Ibrance Prescribing Information. Pfizer Inc. New York, NY. December 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. v.2.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf Accessed April 15, 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228876
Guideline Name	IBS - Diarrhea
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Lotronex (alosetron hydrochloride)
Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women Indicated only for women with severe diarrhea-predominant IBS who have: • chronic IBS symptoms (generally lasting 6 months or longer) • had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and • not responded adequately to conventional therapy. Diarrhea-predominant IBS is severe if it includes diarrhea and one or more of the following: • frequent and severe abdominal pain/discomfort • frequent bowel urgency or fecal incontinence • disability or restriction of daily activities due to IBS. Because of infrequent but serious gastrointestinal adverse reactions associated with Lotronex, the indication is restricted to those patients for whom the benefit-to-risk balance is most favorable. Clinical studies have not been performed to adequately confirm the benefits of Lotronex in men.
Drug Name: Viberzi (eluxadoline)
Irritable bowel syndrome with diarrhea (IBS-D) Indicated in adults for the treatment of IBS-D.

2 . Criteria

Product Name:Brand Lotronex, Generic alosetron	
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LOTRONEX	ALOSETRON HCL TAB 0.5 MG (BASE EQUIV)	52554015100310	Brand
LOTRONEX	ALOSETRON HCL TAB 1 MG (BASE EQUIV)	52554015100320	Brand
ALOSETRON HYDROCHLORIDE	ALOSETRON HCL TAB 0.5 MG (BASE EQUIV)	52554015100310	Generic
ALOSETRON HYDROCHLORIDE	ALOSETRON HCL TAB 1 MG (BASE EQUIV)	52554015100320	Generic

Approval Criteria

1 - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)

AND

2 - Symptoms for at least 6 months [A]

AND

3 - Patient is female

AND

4 - Patient is 18 years of age or older

AND

5 - Trial and failure, contraindication, or intolerance to both of the following:

- antispasmodic agent [eg, Bentyl (dicyclomine)] [2, 6, B]
- antidiarrheal agent [eg, loperamide] [2, 3, 6]

Product Name:Brand Lotronex, Generic alosetron	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LOTRONEX	ALOSETRON HCL TAB 0.5 MG (BASE EQUIV)	52554015100310	Brand
LOTRONEX	ALOSETRON HCL TAB 1 MG (BASE EQUIV)	52554015100320	Brand
ALOSETRON HYDROCHLORIDE	ALOSETRON HCL TAB 0.5 MG (BASE EQUIV)	52554015100310	Generic
ALOSETRON HYDROCHLORIDE	ALOSETRON HCL TAB 1 MG (BASE EQUIV)	52554015100320	Generic

Approval Criteria

1 - Symptoms of IBS continue to persist

AND

2 - Patient demonstrates positive clinical response to therapy as evidenced by one of the following: [1]

- Relief of IBS abdominal pain and discomfort
- Improvement in stool consistency
- Decrease in daily stool frequency
- Moderate or substantial improvement as measured by the Global Improvement Scale [C]

Product Name:Viberzi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIBERZI	ELUXADOLINE TAB 75 MG	52558020000330	Brand
VIBERZI	ELUXADOLINE TAB 100 MG	52558020000340	Brand

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea

AND

2 - Trial and failure, contraindication, or intolerance to both of the following:

- antispasmodic agent [eg, Bentyl (dicyclomine)] [2, 6]
- antidiarrheal agent [eg, Lomotil (diphenoxylate and atropine)] [2, 3, 6]

Product Name:Viberzi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIBERZI	ELUXADOLINE TAB 75 MG	52558020000330	Brand
VIBERZI	ELUXADOLINE TAB 100 MG	52558020000340	Brand

Approval Criteria

1 - Symptoms of IBS continue to persist

AND

2 - Patient demonstrates positive clinical response to therapy as evidenced by both of the following: [D]

- Improvement in the daily worst abdominal pain score
- Reduction in the Bristol Stool Scale

3 . Endnotes

A. Lotronex was removed from the market in late 2000 due to reports of ischemic colitis and severe constipation but has since been re-released with a “black box” warning for use in select cases. [1, 3, 4, 5]
B. Lotronex should be used with caution in debilitated patients, elderly patients, patients with hepatic impairment, and patients taking medications that decrease gastrointestinal motility. [1]
C. The Global Improvement Scale (GIS) assesses multiple symptoms of Irritable Bowel Syndrome (IBS) using a 7-point Likert scale which ranges from symptoms substantially worse to substantially improved. GIS responders were defined as having moderate or substantial improvement in IBS symptoms. [1]
D. The primary endpoint in Studies 1 and 2 to assess the efficacy of Viberzi was defined by both the simultaneous improvement in the daily worse abdominal pain score by ≥30% as compared to the baseline weekly average AND a reduction in the BSS to <5 on at least 50% of the days within a 12-week time interval. [7]

4 . References

1. Lotronex Prescribing Information. Sebela Pharmaceuticals Inc. Roswell, Georgia, CA. July 2016.
2. Lembo A, Sultan S, Chang L, Heidelbaugh JJ, Smalley W, Verne GN. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Diarrhea. Gastroenterology. 2022;163(1):137-151. doi:https://doi.org/10.1053/j.gastro.2022.04.017
3. Wilkins T, Pepitone C, Alex B, Schade RR. Diagnosis and management of IBS in adults. Am Fam Physician. 2012;86(5):419-26.
4. Camiller M, Mayer EA, Drossman DA, et al. Improvement in the pain and bowel function in female irritable bowel patients with alosetron, a 5-HT3 antagonist. Aliment Pharmacol Ther 1999;13(9):1149-5.
5. Chey WD, Chey WY, Health AT, et al. Long-term Safety and Efficacy of Alosetron in Women with Severe Diarrhea-Predominant Irritable Bowel Syndrome. Am J of Gastroenterol 2004;99:2195-2203.
6. American College of Gastroenterology IBS Task Force. Evidence-based position statement on the management of irritable bowel syndrome in North America. Am J Gastroenterol. 2009;104(suppl 1):S1-S35.

7. Viberzi Prescribing Information. Allergan USA, Inc. Madison, NJ. June 2020.
8. Alosetron Prescribing Information. Actavis Pharma, Inc. Parsippany, NJ. January 2016
9. Ford AC, Moayyedi P, Chey WD, Harris LA, Lacy BE, Saito YA, Quigley EMM; ACG Task Force on Management of Irritable Bowel Syndrome. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. Am J Gastroenterol. 2018 Jun;113(Suppl 2):1-18.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228664
Guideline Name	Ibsrela (tenapanor) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ibsrela (tenapanor)
Irritable Bowel Syndrome with Constipation Indicated for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults.

2 . Criteria

Product Name:Ibsrela	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IBSRELA	TENAPANOR HCL TAB 50 MG	52558580100320	Brand

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation (IBS-C)

AND

2 - Used as an adjunct to lifestyle modifications (e.g., increase intake of fibers and fluids, increase physical activity)

AND

3 - Trial and failure, contraindication, or intolerance to ONE the following:

- generic lactulose
- generic polyethylene glycol

AND

4 - Trial and failure, contraindication, or intolerance to Linzess

Product Name:Ibsrela	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IBSRELA	TENAPANOR HCL TAB 50 MG	52558580100320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following:

- Improvement in constipation or stool frequency from baseline
- Decrease in abdominal pain or discomfort

Product Name:Ibsrela	
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
IBSRELA	TENAPANOR HCL TAB 50 MG	52558580100320	Brand

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation (IBS-C)

AND

2 - Used as an adjunct to lifestyle modifications (e.g., increase intake of fibers and fluids, increase physical activity)

AND

3 - Submission of medical records (e.g. chart notes) or paid claims confirming trial and failure (minimum 30 days supply), contraindication, or intolerance to ONE the following:

- generic lactulose
- generic polyethylene glycol

AND

4 - Submission of medical records (e.g. chart notes) or paid claims confirming trial and failure (minimum 30 days supply), contraindication, or intolerance to both of the following:

- Linzess
- generic lubiprostone (Amitiza)

3 . References

1. Ibsrela prescribing information. Ardelyx, Inc. Waltham, MA. May 2021.
2. UpToDate. Wald, A. Treatment of Irritable Bowel Syndrome in Adults. Available at https://www.uptodate.com/contents/treatment-of-irritable-bowel-syndrome-in-adults?search=irritable%20bowel%20syndrome%20constipation&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed March 11, 2023.
3. Chang, L., Sultan, S., et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome with Constipation. Gastroentrology. 2022;11:118-136.Available at https://www.gastrojournal.org/article/S0016-5085(22)00390-0/fulltext, Accessed March 11, 2023.

Iclusig (ponatinib)

Prior Authorization Guideline

Guideline ID	GL-229140
Guideline Name	Iclusig (ponatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/19/2013
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Iclusig (ponatinib)
Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL) 1) Newly diagnosed Ph+ ALL in combination with chemotherapy. This indication is approved under accelerated approval based on minimal residual disease (MRD)-negative complete remission (CR) at the end of induction. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s). 2) As monotherapy in Ph+ ALL for whom no other kinase inhibitors are indicated or T315I-positive Ph+ ALL. **Chronic Myeloid Leukemia (CML)** 1) Indicated for the treatment of adult patients with chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors. 2) Indicated for the treatment of adult patients with Accelerated phase (AP) or blast phase (BP) Chronic Myeloid Leukemia (CML) for whom no other kinase inhibitors are indicated. 3) Indicated for the treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) Limitations of Use: Iclusig is not

indicated and is not recommended for the treatment of patients with newly diagnosed CP-CML

2 . Criteria

Product Name:Iclusig	
Diagnosis	Chronic Myelogenous Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ICLUSIG	PONATINIB HCL TAB 10 MG (BASE EQUIV)	21531875100315	Brand
ICLUSIG	PONATINIB HCL TAB 15 MG (BASE EQUIV)	21531875100320	Brand
ICLUSIG	PONATINIB HCL TAB 30 MG (BASE EQUIV)	21531875100330	Brand
ICLUSIG	PONATINIB HCL TAB 45 MG (BASE EQUIV)	21531875100340	Brand

Approval Criteria

1 - Diagnosis of chronic myelogenous leukemia (CML)

Product Name:Iclusig	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ICLUSIG	PONATINIB HCL TAB 10 MG (BASE EQUIV)	21531875100315	Brand
ICLUSIG	PONATINIB HCL TAB 15 MG (BASE EQUIV)	21531875100320	Brand

ICLUSIG	PONATINIB HCL TAB 30 MG (BASE EQUIV)	21531875100330	Brand
ICLUSIG	PONATINIB HCL TAB 45 MG (BASE EQUIV)	21531875100340	Brand

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL)

AND

2 - One of the following [1]:

2.1 Used in combination with chemotherapy up to 20 cycles

OR

2.2 Used as monotherapy in patients where one of the following applies:

- No other kinase inhibitors are indicated
- Disease is T315I-positive Ph+ ALL

Product Name:Iclusig	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ICLUSIG	PONATINIB HCL TAB 10 MG (BASE EQUIV)	21531875100315	Brand
ICLUSIG	PONATINIB HCL TAB 15 MG (BASE EQUIV)	21531875100320	Brand
ICLUSIG	PONATINIB HCL TAB 30 MG (BASE EQUIV)	21531875100330	Brand
ICLUSIG	PONATINIB HCL TAB 45 MG (BASE EQUIV)	21531875100340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Resistance in CP-CML while on prior TKI therapy, was defined as failure to achieve either a complete hematologic response (by 3 months), a minor cytogenetic response (by 6 months), or a major cytogenetic response (by 12 months). Patients with CP-CML who experienced a loss of response or development of a kinase domain mutation in the absence of a complete cytogenetic response or progression to AP-CML or BP-CML at any time on prior TKI therapy were also considered resistant. Resistance in AP-CML, BP-CML, and Ph+ALL was defined as failure to achieve either a major hematologic response (by 3 months in AP-CML, and by 1 month in BP-CML and Ph+ALL), loss of major hematologic response (at any time), or development of a kinase domain mutation in the absence of a complete major hematologic response while on prior TKI therapy. Intolerance was defined as the discontinuation of prior TKI therapy due to toxicities despite optimal management in the absence of a complete cytogenetic response in patients with CP-CML or major hematologic response for patients with APCML, BP-CML, or Ph+ALL. [1]

4 . References

1. Iclusig Prescribing Information. ARIAD Pharmaceuticals, Inc. Cambridge, MA. March 2024.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Idhifa (enasidenib)

Prior Authorization Guideline

Guideline ID	GL-233203
Guideline Name	Idhifa (enasidenib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/25/2017
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Idhifa (enasidenib)
Relapsed or Refractory Acute Myeloid Leukemia (AML) Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test.

2 . Criteria

Product Name:Idhifa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IDHIFA	ENASIDENIB MESYLATE TAB 50 MG (BASE EQUIVALENT)	21535030200320	Brand
IDHIFA	ENASIDENIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21535030200340	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH2 assay) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Idhifa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IDHIFA	ENASIDENIB MESYLATE TAB 50 MG (BASE EQUIVALENT)	21535030200320	Brand
IDHIFA	ENASIDENIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21535030200340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Idhifa Prescribing Information. Celgene Corporation. Summit, NJ. December 2023.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228437
Guideline Name	Igalmi (dexmedetomidine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Igalmi (dexmedetomidine)
Agitation Indicated for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. Limitations of Use: The safety and effectiveness of Igalmi has not been established beyond 24 hours from the first dose.

2 . Criteria

Product Name:Igalmi	
Approval Length	14 Days [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IGALMI	DEXMEDETOMIDINE HCL FILM 120 MCG	60206030108220	Brand
IGALMI	DEXMEDETOMIDINE HCL FILM 180 MCG	60206030108230	Brand

Approval Criteria

1 - One of the following diagnoses:

- Schizophrenia
- Bipolar I or II disorder

AND

2 - For the treatment of acute agitation [B, 1]

AND

3 - Trial and failure, contraindication or intolerance to at least two products used in acute agitation (e.g., olanzapine, ziprasidone) [C, 2-5]

AND

4 - Patient is currently being managed with maintenance medication for their underlying disorder (e.g., aripiprazole, olanzapine, quetiapine, lithium, valproic acid)

3 . Endnotes

A. The safety and effectiveness of Igalmi has not been established beyond 24 hours from the 1st dose. Clinical studies were done on patients who were admitted to a clinical research unit or a hospital and remained under medical supervision for at least 24 hours following treatment. If agitation persists after the initial dose, up to two additional doses may be administered at least two hours apart. [13]
B. We consider agitation to be a psychiatric emergency. Agitation is a state of motor restlessness or excitement and is often accompanied by mental tension and irritability. [14]

C. With the emergence of second generation (atypical) antipsychotics(SGA's), the expert consensus-based guidelines recommend SGA's as 1st line therapy [2]

4 . References

1. Wilson, M., Pepper, D. et al. The Psychopharmacology of Agitation: Consensus Statement of the American Association for Emergency Psychiatry Project BETA Psychopharmacology Workgroup. West J Emerg Med. 2012 Feb; 13(1): 26–34. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3298219/. Accessed June 6, 2022.
2. Garriga M, Pacchiarotti I, Kasper S, Zeller SL, Allen MH, Vazquez G, et al. Assessment and management of agitation in psychiatry: expert consensus. World J Biol Psychiatry. (2016) 17:86–128. doi: 10.3109/15622975.2015.1132007. Accessed June 6, 2022.
3. Zeller, S., Citrome, L. Managing Agitation Associated with Schizophrenia and Bipolar Disorder in the Emergency Setting. West J Emerg Med. 2016 Mar; 17(2): 165–172. doi: 10.5811/westjem.2015.12.28763. accessed June 6, 2022.
4. Miller, J. Managing acute agitation and aggression in the world of drug shortages. Mental Health Clinician (2021) 11 (6): 334–346. https://doi.org/10.9740/mhc.2021.11.334. Accessed June 6, 2022.
5. Schleifer, J. Management of acute agitation in psychosis: an evidence-based approach in the USA. Jan 2, 2018. Available at https://www.cambridge.org/core/journals/advances-in-psychiatric-treatment/article/management-of-acute-agitation-in-psychosis-an-evidencebased-approach-in-the-usa/AC36BE73F3238B40EBDFC719B62D93E6. Accessed June 6, 2022.
6. Roppolo, L., Morris, D. et al. Improving the management of acutely agitated patients in the emergency department through implementation of Project BETA (Best Practices in the Evaluation and Treatment of Agitation). https://doi.org/10.1002/emp2.12138. Accessed June 6, 2022.
7. Zyprexa Prescribing Information. Lilly USA, LLC. Indianapolis, IN. February 2022.
8. Risperdal Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. March 2022..
9. Geodon Prescribing Information. Pfizer Inc. New York, NY. February 2022.
10. Abilify Prescribing Information. Otsuka America Pharmaceutical, Inc. Rockville, MD. August 2021.
11. Seroquel Prescribing Information. AstraZeneca Pharmaceuticals, LP. Wilmington, DE. January 2022.
12. Saphris Prescribing Information. Breckenridge Pharmaceuticals, Inc. Berlin, CT. July 2021.
13. Igalmi Prescribing Information. BioXcel Therapeutics, Inc. New Haven, CT. April 2022.
14. Marder, S. Uptodate. Psychosis in adults: Initial management. Available at https://www.uptodate.com/contents/psychosis-in-adults-initial-management?sectionName=INITIAL%20MANAGEMENT&search=AGITITAION%20IN%20SCHIZOPHRENIA&topicRef=14805&anchor=H4035521878&source=see_link#H4035521878. Accessed June 6, 2022.
15. Curry, A., Malas, N., Mroczkowski, M., et al. Updates in the Assessment and Management of Agitation. Available at: https://focus.psychiatryonline.org/doi/10.1176/appi.focus.20220064. Accessed June 13, 2024.

16. UptoDate. Assessment and emergency management of the acutely agitated or violent adult. Available at: https://www.uptodate.com/contents/assessment-and-emergency-management-of-the-acutely-agitated-or-violent-adult. Accessed June 13, 2024.

Prior Authorization Guideline

Guideline ID	GL-228631
Guideline Name	Ilaris (canakinumab injection)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ilaris (canakinumab injection)
Periodic Fever Syndromes: Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever(FMF) Indicated for the treatment of the following autoinflammatory Periodic Fever Syndromes: Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including, Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS); Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients; Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients; Familial Mediterranean Fever (FMF) in adult and pediatric patients. **Systemic Juvenile Idiopathic Arthritis (SJIA)** Indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older. **Still's disease (Adult-Onset Still's Disease [AOSD])** Indicated for the treatment of active Still's disease, including Adult-Onset Still's Disease (AOSD) in patients aged 2 years and older.

Gout Flares Indicated for the symptomatic treatment of adult patients with gout flares in whom nonsteroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

2 . Criteria

Product Name:Ilaris	
Diagnosis	Periodic Fever Syndromes [Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency(MKD), Familial Mediterranean Fever(FMF)]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ILARIS	CANAKINUMAB SUBCUTANEOUS INJ 150 MG/ML	66460020002015	Brand

Approval Criteria

1 - Diagnosis of one of the following periodic fever syndromes:

- cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)
- tumor necrosis factor (TNF) receptor associated periodic syndrome (TRAPS)
- hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS/mevalonate kinase deficiency (MKD)
- familial mediterranean fever (FMF)

AND

2 - Prescribed by or in consultation with one of the following:

- Immunologist

- Allergist
- Dermatologist
- Rheumatologist
- Neurologist

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name:Ilaris	
Diagnosis	Periodic Fever Syndrome [CAPS, TRAPS, HIDS/MKD, FMF]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ILARIS	CANAKINUMAB SUBCUTANEOUS INJ 150 MG/ML	66460020002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name:Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ILARIS	CANAKINUMAB SUBCUTANEOUS INJ 150 MG/ML	66460020002015	Brand

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [1, 2]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name:Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ILARIS	CANAKINUMAB SUBCUTANEOUS INJ 150 MG/ML	66460020002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 2]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name:Ilaris	
Diagnosis	Still's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ILARIS	CANAKINUMAB SUBCUTANEOUS INJ 150 MG/ML	66460020002015	Brand

Approval Criteria

1 - Diagnosis of Still's Disease, including Adult-Onset Still's Disease (AOSD)

AND

2 - Trial and failure, contraindication, or intolerance to one of the following: [1-3]

- Corticosteroids (e.g., prednisone)
- Methotrexate
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name:Ilaris	
Diagnosis	Still's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ILARIS	CANAKINUMAB SUBCUTANEOUS INJ 150 MG/ML	66460020002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name:Ilaris	
Diagnosis	Gout Flares
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ILARIS	CANAKINUMAB SUBCUTANEOUS INJ 150 MG/ML	66460020002015	Brand

Approval Criteria

1 - Diagnosis of gout flares

AND

2 - Trial and failure, contraindication, or intolerance to ALL of the following [1, 6]:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

- Colchicine
- Corticosteroids (e.g., prednisone)

AND

3 - Patient has not received Ilaris in the last 12 weeks [A]

AND

4 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Nephrologist

3 . Definitions

Definition	Description
Cryopyrin-Associated Periodic Syndromes (CAPS):	A group of rare, autosomal dominantly inherited auto-inflammatory conditions comprising of Familial-Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or also known as Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA), which are caused by the CIAS1 gene mutation and characterized by recurrent symptoms (urticaria-like skin lesions, fever chills, arthralgia, profuse sweating, sensorineural hearing/vision loss, and increased inflammation markers the blood). Approximately 300 people in the United States are affected by CAPS. [1, 4, 5]
Familial Cold Autoinflammatory Syndrome (FCAS):	The mildest form of CAPS, is characterized by cold-induced, daylong episodes of fever associated with rash, arthralgia, headaches and less frequently conjunctivitis, but without other signs of CNS inflammation. Symptoms usually begin during the first 6 months of life and are predominantly triggered by cold exposure. Duration of episodes usually is less than 24 hours. [5]

Muckle-Wells Syndrome (MWS):	A subtype of CAPS, which is characterized by episodic attacks of inflammation associated with a generalized urticaria-like rash, fever, malaise, arthralgia, and progressive hearing loss. Duration of symptoms usually lasts from 24-48 hours. [5]

4 . Endnotes

A. The recommended dose of Ilaris for adult patients with a gout flare is 150 mg administered subcutaneously. In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of Ilaris may be administered [1].

5 . References

1. Ilaris Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2023.
2. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.
3. Mimura T, Kondo Y, Ohta A et al. Evidence-based clinical practice guideline for adult Still's disease. Mod Rheumatol. 2018;28(5):736-757.
4. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al. Use of canakinumab in the cryopyrin-associated periodic syndrome. N Engl J Med. 2009;360(23):2416-25.
5. Aksentijevich I, Putnam CD, Remmers EF, et al. Clinical continuum of cryopyrinopathies: novel CIAS1 mutations in North-American patients and a new cryopyrin model. Arthritis Rheum. 2007;56(4):1273-85.
6. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology guideline for the management of gout. Arthritis Care Res. 2020;72(6):744-760.

6 . Revision History

Date	Notes
11/7/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-229081
Guideline Name	Ilumya (tildrakizumab-asmn) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Ilumya	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ILUMYA	TILDRAKIZUMAB-ASMN SUBCUTANEOUS SOLN PREF SYRINGE 100 MG/ML	9025058010E520	Brand

Approval Criteria

1 - Diagnosis of moderate-to-severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Trial and failure, contraindication, or intolerance to THREE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product*
- One formulary ustekinumab product*
- Cosentyx (secukinumab)
- Skyrizi (risankizumab)
- Tremfya (guselkumab)

- Otezla (apremilast)
- Sotyktu (deucravacitinib)

AND

5.1.2 Trial and failure, contraindication, or intolerance to Bimzelx (bimekizumab-bkzx)

OR

5.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

Notes	* For review process only: Refer to the table in the Background section for carrier-specific formulary products

Product Name:Ilumya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ILUMYA	TILDRAKIZUMAB-ASMN SUBCUTANEOUS SOLN PREF SYRINGE 100 MG/ML	9025058010E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Ilumya	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ILUMYA	TILDRAKIZUMAB-ASMN SUBCUTANEOUS SOLN PREF SYRINGE 100 MG/ML	9025058010E520	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderate-to-severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to THREE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product*
- One formulary ustekinumab product*
- Cosentyx (secukinumab)
- Skyrizi (risankizumab)
- Tremfya (guselkumab)
- Otezla (apremilast)
- Sotyktu (deucravacitinib)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Bimzelx (bimekizumab-bkzx)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

2 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products **Adalimumab-adaz** **Hyrimoz** **Hadlima** **Adalimumab-fkjp** **Formulary Ustekinumab Products**

Formulary Ustekinumab Products
Stelara (ustekinumab)

3 . References

1. Ilumya prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. April 2024.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

4 . Revision History

Date	Notes
12/20/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-228878
Guideline Name	Imbruvica (ibrutinib) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Imbruvica (ibrutinib)
Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) with 17p deletion** Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic leukemia (SLL) with 17p deletion **Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma** Indicated for the treatment of adult patients with Waldenström’s macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma [2] **Chronic graft versus host disease (cGVHD)** Indicated for the treatment of adult and pediatric patients age 1 year and older with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

2 . Criteria

Product Name:Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- chronic lymphocytic leukemia
- small lymphocytic lymphoma

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name:Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name:Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- chronic lymphocytic leukemia
- small lymphocytic lymphoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name:Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- chronic lymphocytic leukemia
- small lymphocytic lymphoma

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

Product Name:Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

Product Name:Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of Waldenstrom's Macroglobulinemia

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name:Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name:Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of Waldenstrom's Macroglobulinemia

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name:Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

1 - Diagnosis of Waldenstrom's Macroglobulinemia

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

Product Name:Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

Product Name:Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of chronic graft versus host disease (cGVHD)

AND

2 - Patient is 1 year of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate)

AND

4 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name:Imbruvica 140mg tablet, Imbruvica 280mg tablet

Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name:Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of chronic graft versus host disease (cGVHD)

AND

2 - Patient is 1 year of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name:Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

1 - Diagnosis of chronic graft versus host disease (cGVHD)

AND

2 - Patient is 1 year of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate)

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

Product Name:Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

3 . References

1. Imbruvica Prescribing Information. Pharmacyclics, Inc. Sunnyvale, CA. August 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233330
Guideline Name	Imdelltra (tarlatamab-dlle)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/18/2025
P&T Approval Date:	7/17/2024
P&T Revision Date:	

1 . Indications

Drug Name: Imdelltra (tarlatamab-dlle)
Small cell lung cancer (SCLC) Indicated for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name:Imdelltra

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMDELLTRA	TARLATAMAB-DLLE FOR IV INFUSION 1 MG	21352078202120	Brand
IMDELLTRA	TARLATAMAB-DLLE FOR IV INFUSION 10 MG	21352078202130	Brand

Approval Criteria

1 - Diagnosis of extensive stage small cell lung cancer (ES-SCLC)

AND

2 - Disease has progressed on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin)

AND

3 - Patient has an Eastern Cooperative Oncology Group (ECOG) Score of 0 or 1

Product Name:Imdelltra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMDELLTRA	TARLATAMAB-DLLE FOR IV INFUSION 1 MG	21352078202120	Brand
IMDELLTRA	TARLATAMAB-DLLE FOR IV INFUSION 10 MG	21352078202130	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Imdelltra Prescribing Information. Amgen Inc. Thousand Oaks, CA. May 2024.

4 . Revision History

Date	Notes
2/18/2025	Quartz commercial copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-228881
Guideline Name	Immune Globulins - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Bivigam (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated for the treatment of adults and pediatric patients 2 years of age and older with primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Flebogamma 5% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated in adults and pediatric patients 2 years of age and older for the treatment of primary immunodeficiency (PI), including the humoral immune defects in common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency, and Wiskott-Aldrich syndrome.
Drug Name: Flebogamma 10% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated as replacement therapy in primary immunodeficiency (PI) including the humoral immune defects in common variable immunodeficiency, xlinked agammaglobulinemia, severe combined immunodeficiency, and

Wiskott-Aldrich syndrome.

Chronic Primary Immune Thrombocytopenia (ITP) Indicated for the treatment of patients 2 years of age and older with chronic primary ITP to raise platelet count.

Drug Name: Gamastan (immune globulin [Human])

Measles (Rubeola) Indicated to prevent or modify measles in a susceptible person exposed fewer than 6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously. Gamastan may be especially indicated for susceptible household contacts of measles patients, particularly contacts under 1 year of age, for whom the risk of complications is highest. Gamastan is also indicated for pregnant women without evidence of immunity. Gamastan and measles vaccine should not be given at the same time. If a child is older than 12 months and has received Gamastan, he should be given measles vaccine about 5 months later when the measles antibody titer will have disappeared. If a susceptible child exposed to measles is immunocompromised, give Gamastan immediately.

Rubella Indicated to modify rubella in exposed women who will not consider a therapeutic abortion. Some studies suggest that the use of Gamastan in exposed, susceptible women can lessen the likelihood of infection and fetal damage; therefore, Gamastan may benefit those women who will not consider a therapeutic abortion. Do not give Gamastan for routine prophylaxis of rubella in early pregnancy to an unexposed woman.

Hepatitis A Indicated for prophylaxis following exposure to hepatitis A. The prophylactic value of Gamastan is greatest when given before or soon after exposure to hepatitis A. Gamastan is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.

Varicella Indicated to modify varicella. Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella Zoster Immune globulin (Human) [VZIG]. If VZIG is unavailable, Gamastan, promptly given, may also modify varicella.

Drug Name: Privigen (immune globulin [Human])

Chronic Immune Thrombocytopenic Purpura (ITP) Indicated for the treatment of patients age 15 years and older with chronic ITP to raise platelet counts.

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment. Limitation of Use: Privigen maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with Privigen in order

to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

Drug Name: Gammagard S/D (immune globulin [Human])

Kawasaki Disease Indicated for the prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients.

B-cell Chronic Lymphocytic Leukemia (CLL) Indicated for prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia (CLL).

Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of adult chronic idiopathic thrombocytopenic purpura to increase platelet count and to prevent and/or to control bleeding.

Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency (PI) associated with defects in humoral immunity, in adults and children two years and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Gammaked and Gamunex-C (immune globulin [Human])

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of CIDP in adults to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.

Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of adults and children with idiopathic thrombocytopenic purpura to raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery.

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Immune globulin products (IVIG)

Off Label Uses: Bone Marrow Transplant (BMT) [6, 19-22] Has been used to decrease the incidence of infections and graft versus host disease (GVHD) in patients 20 years of age and older who underwent bone marrow transplantation.

Dermatomyositis [6, 23] In patients with treatment-resistant dermatomyositis, IVIG therapy resulted in improvements in muscle strength and neuromuscular symptoms.

Multifocal Motor Neuropathy (MMN) [6, 24, 25, 26] In placebo-controlled trials, IVIG has been shown to improve muscle strength and reduce disability and conduction block in patients with MMN.

HIV [6, 27, 28] Used to decrease the frequency of serious and minor bacterial infections; the frequency of hospitalization; and to increase the time free of serious bacterial infections in patients with HIV.

Guillain-Barre Syndrome [6, 29] Considered to be equally effective as plasma exchange for the treatment of Guillain-Barre Syndrome.

Lambert-Eaton Myasthenic Syndrome [6, 30] Considered a first-line treatment option to treat the refractory pattern of weakness seen in patients with LEMS.

Myasthenia Gravis [6, 34] A clinical study comparing IVIG with plasma exchange did not show a significant difference between the two treatments in patients with myasthenia gravis exacerbation. Several open studies support beneficial effects of IVIG in treating myasthenia gravis.

Relapsing Remitting Multiple Sclerosis [6, 35, 36] Published studies indicate that IVIG may reduce the frequency of acute exacerbations and provide symptomatic relief in patients with relapsing-remitting forms of multiple sclerosis.

Stiff-Person Syndrome [6, 64, 65] The efficacy of IVIG for the treatment of stiff-person syndrome was demonstrated in a randomized, double-blind, placebo-controlled, crossover trial.

Polymyositis [6, 23] Found to be effective in reversing chronic polymyositis previously unresponsive to immunosuppressive therapy.

Drug Name: Gammagard Liquid (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Multifocal Motor Neuropathy (MMN) Indicated as a maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy (MMN).

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated as a therapy to improve neuromuscular disability and impairment in adult patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). Limitation of Use: Gammagard Liquid has not been studied in immunoglobulin-naive patients with CIDP. Gammagard Liquid maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with Gammagard Liquid in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

Drug Name: Gammaplex (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated for replacement therapy in primary humoral immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Immune Thrombocytopenic Purpura (ITP) Indicated for the treatment of adults with chronic immune thrombocytopenic purpura (ITP) to raise platelet counts.

Drug Name: Octagam 10% (immune globulin [Human])

Chronic Immune Thrombocytopenic Purpura Indicated in chronic immune thrombocytopenic purpura to rapidly raise platelet counts to control or prevent bleeding in adults.

Dermatomyositis Indicated for the treatment of dermatomyositis in adults.

Drug Name: Octagam 5% (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. These include, but are not limited to: congenital agammaglobulinemia, X-linked agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Cytogam (cytomegalovirus immune globulin [Human])

Cytomegalovirus Indicated for the prophylaxis of cytomegalovirus disease associated with transplantation of kidney, lung, liver, pancreas and heart. In transplants of these organs other than kidney from CMV seropositive donors into seronegative recipients, prophylactic CMV-IGIV should be considered in combination with ganciclovir.

Drug Name: Varizig (varicella zoster immune globulin [Human] solution)

Post-exposure prophylaxis of varicella Indicated for post-exposure prophylaxis of varicella in high risk individuals. High risk groups include: immunocompromised children and adults, newborns of mothers with varicella shortly before or after delivery, premature infants, neonates and infants less than one year of age, adults without evidence of immunity, pregnant women. Limitations of Use: There is no convincing evidence that Varizig reduces the incidence of chickenpox infection after exposure to VZV. There is no convincing evidence that established infections with VZV can be modified by Varizig administration. There is no indication for the prophylactic use of Varizig in immunodeficient children or adults when there is a past history of varicella, unless the patient is undergoing bone marrow transplantation.

Drug Name: Hizentra (immune globulin [Human]) for subcutaneous administration

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia,

common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment. Limitations of Use: Hizentra maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Maintenance therapy beyond these periods should be individualized based upon the patient's response and need for continued therapy.

Drug Name: Panzyga (immune globulin intravenous [Human] - ifas)

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Immune Thrombocytopenia (ITP) Indicated for the treatment of adult patients with ITP to raise platelet counts to control or prevent bleeding.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment.

Drug Name: Cuvitru (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Cutaquig (Immune globulin subcutaneous [Human] - hipp)

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Xembify (immune globulin subcutaneous, human - klhw)

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Asceniv (immune globulin intravenous, human - slra)

Primary Immunodeficiency Disorders Indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age). PI includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID).
Drug Name: HyQvia (immune globulin with recombinant human hyaluronidase) for subcutaneous administration
Primary Immunodeficiency Indicated for the treatment of Primary Immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)** Indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults.
Drug Name: Alyglo (immune globulin intravenous, human-stwk)
Primary Immunodeficiency Disorders Indicated for the treatment of primary humoral immunodeficiency (PI) in adults. This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiency (SCID).

2 . Criteria

Product Name:Intravenous or subcutaneous immune globulins (IVIG or SCIG)	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201020	
Immune globulin (SCIG)	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ	191000202020	

Immune globulin (IVIG/SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	
BIVIGAM			
FLEBOGAMMA DIF			
OCTAGAM			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
HIZENTRA			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 1 GM/6ML	19100020572021	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 1.65 GM/10ML	19100020572025	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 2 GM/12ML	19100020572030	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 3.3 GM/20ML	19100020572035	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 4 GM/24ML	19100020572040	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 8 GM/48ML	19100020572055	Brand
CUVITRU			
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 1 GM/5ML	19100020642020	Brand
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 2 GM/10ML	19100020642025	Brand
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 4 GM/20ML	19100020642030	Brand
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 10 GM/50ML	19100020642040	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand

HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 1 GM/5ML	1910002020E520	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 2 GM/10ML	1910002020E530	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 4 GM/20ML	1910002020E540	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome [1, 3, 5, 6, 40, 44, 48-64, I, J]

AND

2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [56]

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome [1, 3, 5, 6, 40, 44, 48-64, I, J]

AND

2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [56]

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:HyQvia	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYQVIA	IMMUN GLOB INJ 2.5 GM/25ML-HYALURON INJ 200 UNT/1.25 ML KIT	19990002356420	Brand
HYQVIA	IMMUN GLOB INJ 5 GM/50ML-HYALURON INJ 400 UNT/2.5 ML KIT	19990002356425	Brand
HYQVIA	IMMUN GLOB INJ 10 GM/100ML-HYALURON INJ 800 UNT/5 ML KIT	19990002356430	Brand
HYQVIA	IMMUN GLOB INJ 20 GM/200ML-HYALURON INJ 1600 UNT/10 ML KIT	19990002356440	Brand
HYQVIA	IMMUN GLOB INJ 30 GM/300ML-HYALURON INJ 2400 UNT/15 ML KIT	19990002356450	Brand

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome

AND

2 - Patient is 2 years of age or older

AND

3 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [56]

3.1 Documented failure to produce antibodies to specific antigens

OR

3.2 History of significant recurrent infections

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulins (IVIG)	
Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			

FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [3, 5, 45, 51-53, 69]

AND

2 - Documented platelet count of less than 50 x 10^9 / L [66]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga

- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [3, 5, 45, 51-53, 69]

AND

2 - Documented platelet count of less than 50 x 10^9 / L [66]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam

- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulins (IVIG)	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand

ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Kawasaki Disease [5]

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand

ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Kawasaki Disease [5]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulins (IVIG)	
Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 10-14]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201020	Brand

Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 500 mg/dL) [13, 14, 59, B]

OR

2.2 History of bacterial infection(s) associated with B-cell CLL [13, 14, 59, B]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 10-14]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 500 mg/dL) [13, 14, 59, B]

OR

2.2 History of bacterial infection(s) associated with B-cell CLL [13,14, 59, A]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG), Hizentra, HyQvia	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15, 17, 18, 41, 45, 55, 78, 79, C, H]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN)IV SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
HIZENTRA			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 1 GM/5ML	1910002020E520	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 2 GM/10ML	1910002020E530	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 4 GM/20ML	1910002020E540	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 1 GM/5ML	19100020202050	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 2 GM/10ML	19100020202054	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 4 GM/20ML	19100020202058	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 10 GM/50ML	19100020202065	Brand
HYQVIA	IMMUN GLOB INJ 2.5 GM/25ML-HYALURON INJ 200 UNT/1.25 ML KIT	19990002356420	Brand
HYQVIA	IMMUN GLOB INJ 5 GM/50ML-HYALURON INJ 400 UNT/2.5 ML KIT	19990002356425	Brand
HYQVIA	IMMUN GLOB INJ 10 GM/100ML-HYALURON INJ 800 UNT/5 ML KIT	19990002356430	Brand

HYQVIA	IMMUN GLOB INJ 20 GM/200ML-HYALURON INJ 1600 UNT/10 ML KIT	19990002356440	Brand
HYQVIA	IMMUN GLOB INJ 30 GM/300ML-HYALURON INJ 2400 UNT/15 ML KIT	19990002356450	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [58, C]:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:

1.2.1 Progressive or relapsing motor impairment of more than one limb

OR

1.2.2 Progressive or relapsing sensory impairment of more than one limb

AND

1.3 Electrophysiologic findings when three of the following four criteria are present:

- Partial conduction block of 1 or more motor nerve
- Reduced conduction velocity of 2 or more motor nerves
- Prolonged distal latency of 2 or more motor nerves
- Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG), Hizentra, HyQvia	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15, 17, 18, 41, 45, 55, 78, 79, C, H]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN)IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			

GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
HIZENTRA			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 1 GM/5ML	1910002020E520	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 2 GM/10ML	1910002020E530	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 4 GM/20ML	1910002020E540	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 1 GM/5ML	19100020202050	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 2 GM/10ML	19100020202054	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 4 GM/20ML	19100020202058	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 10 GM/50ML	19100020202065	Brand
HYQVIA	IMMUN GLOB INJ 2.5 GM/25ML-HYALURON INJ 200 UNT/1.25 ML KIT	19990002356420	Brand
HYQVIA	IMMUN GLOB INJ 5 GM/50ML-HYALURON INJ 400 UNT/2.5 ML KIT	19990002356425	Brand
HYQVIA	IMMUN GLOB INJ 10 GM/100ML-HYALURON INJ 800 UNT/5 ML KIT	19990002356430	Brand
HYQVIA	IMMUN GLOB INJ 20 GM/200ML-HYALURON INJ 1600 UNT/10 ML KIT	19990002356440	Brand
HYQVIA	IMMUN GLOB INJ 30 GM/300ML-HYALURON INJ 2400 UNT/15 ML KIT	19990002356450	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as measured by an objective scale (e.g., Modified Rankin, Medical Research Council [MRC] scale) [58, H, P]

AND

2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect [P]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15, 17, 18, 41, 45, 55, 78, 79, C, H]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [58, C]:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:

1.2.1 Progressive or relapsing motor impairment of more than one limb

OR

1.2.2 Progressive or relapsing sensory impairment of more than one limb

AND

1.3 Electrophysiologic findings when three of the following four criteria are present:

- Partial conduction block of 1 or more motor nerve
- Reduced conduction velocity of 2 or more motor nerves
- Prolonged distal latency of 2 or more motor nerves
- Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Gamastan	
Diagnosis	Hepatitis A
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMASTAN	IMMUNE GLOBULIN (HUMAN) IM INJ	19100020002200	Brand

Approval Criteria

1 - For prophylaxis of Hepatitis A before or soon after exposure [40, 74]

AND

2 - Patient does not have clinical manifestations of hepatitis A [40, 74]

AND

3 - Patient does not have exposure to hepatitis A for more than 2 weeks previously [40, 74]

Product Name:Gamastan	
Diagnosis	Measles (Rubeola)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

GAMASTAN	IMMUNE GLOBULIN (HUMAN) IM INJ	19100020002200	Brand

Approval Criteria

1 - For use in susceptible individuals exposed to measles fewer than 6 days previously [40, 74]

AND

2 - Patient is not receiving measles vaccine at the same time [40, 74]

Product Name:Gamastan	
Diagnosis	Varicella
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMASTAN	IMMUNE GLOBULIN (HUMAN) IM INJ	19100020002200	Brand

Approval Criteria

1 - For passive immunization against varicella [40, 74]

AND

2 - Patient is immunosuppressed [40, 74]

AND

3 - Varicella Zoster Immune Globulin (Human) vaccine is not available

Product Name:Gamastan

Diagnosis	Rubella
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMASTAN	IMMUNE GLOBULIN (HUMAN) IM INJ	19100020002200	Brand

Approval Criteria

1 - For pregnant women who are exposed or susceptible to Rubella [40, 74]

AND

2 - Patient will not consider a therapeutic abortion [40, 74]

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Bone Marrow Transplantation (off-label) [19-22]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			

GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Confirmed allogeneic bone marrow transplant within the last 100 days [19-21, D]

AND

2 - Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL) [19, D]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Bone Marrow Transplantation (off-label) [19-22]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Confirmed allogeneic bone marrow transplant within the last 100 days [19-21, D]

AND

2 - Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL) [19, D]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga

- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	HIV (off-label) [60, 61, 86]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand

ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of HIV disease [60, 61, K]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 400 mg/dL) [75, L]

OR

2.2 Functional antibody deficiency as demonstrated by one of the following: [60]

- Poor specific antibody titers
- Recurrent bacterial infections

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	HIV (off-label) [60, 61, 86]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of HIV disease [60, 61, K]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 400 mg/dL) [75, L]

OR

2.2 Functional antibody deficiency as demonstrated by one of the following: [60]

- Poor specific antibody titers
- Recurrent bacterial infections

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [25, 26]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			

PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [57, 67, 68, N]:

1.1 Weakness with slowly progressive or stepwise progressive course over at least one month

AND

1.2 Asymmetric involvement of two or more nerves

AND

1.3 Absence of both of the following:

1.3.1 Motor neuron signs

AND

1.3.2 Bulbar signs

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [25, 26]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			

PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale] [57, 68]

AND

2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Diagnosis	Multifocal Motor Neuropathy (off-label) [25, 26]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [57, 67, 68, N]:

1.1 Weakness with slowly progressive or stepwise progressive course over at least one month

AND

1.2 Asymmetric involvement of two or more nerves

AND

1.3 Absence of both of the following:

1.3.1 Motor neuron signs

AND

1.3.2 Bulbar signs

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [35, 36]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			

GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of relapsing remitting multiple sclerosis (RRMS) [6, 35, 36, G]

AND

2 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy [6, 35, 36, G, M, O]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following agents: [36, G, M, O]

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Betaseron (interferon beta-1b)*
- Copaxone/Glatopa (glatiramer acetate)*
- Extavia (interferon beta-1b)*
- Gilenya (Fingolimod)*
- Lemtrada (alemtuzumab)*
- Plegridy (peginterferon beta-1a)*
- Rebif (interferon beta-1a)*

- Tecfidera (dimethyl fumarate)*
- Tysabri (natalizumab)*

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Notes	*This agent may require prior authorization.

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [35, 36]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			

GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - The prescriber maintains and provides chart documentation of the patient's evaluation, including both of the following [6, 35, 36, O]:

1.1 Findings of interval examination including neurological deficits incurred

AND

1.2 Assessment of disability (e.g., Expanded Disability Status Score [EDSS], Functional Systems Score [FSS], Multiple Sclerosis Functional Composite [MSFC], Disease Steps [DS])

AND

2 - Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS) [6, 35, 36]

AND

3 - Documentation of decreased number of relapses since starting immune globulin therapy [6, 35, 36]

AND

4 - Diagnosis continues to be the relapsing-remitting form of MS (RRMS)

AND

5 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

6 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

7 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [35, 36]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of relapsing remitting multiple sclerosis (RRMS)) [6, 35, 36, G]

AND

2 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy [6, 35, 36, G, M, O]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following agents: [36, G, M, O]

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Betaseron (interferon beta-1b)*
- Copaxone/Glatopa (glatiramer acetate)*
- Generic dimethyl fumarate
- Gilenya (Fingolimod)*
- Lemtrada (alemtuzumab)*
- Tysabri (natalizumab)*

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard

- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Notes	*This agent may require prior authorization.

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Myasthenia Gravis Exacerbation (off-label) [34]
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand

ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis [34, 55, F, R]

AND

2 - Evidence of myasthenic exacerbation, defined by one of the following symptoms in the last month: [34, 55, F, R]

2.1 Difficulty swallowing

OR

2.2 Acute respiratory failure

OR

2.3 Major functional disability responsible for the discontinuation of physical activity

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine), unless contraindicated, will be used for long-term management of myasthenia gravis [34, 55, F, R]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Myasthenia Gravis Exacerbation (off-label) [34]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis [34, 55, F, R]

AND

2 - Evidence of myasthenic exacerbation, defined by one of the following symptoms in the last month: [34, 55, F, R]

2.1 Difficulty swallowing

OR

2.2 Acute respiratory failure

OR

2.3 Major functional disability responsible for the discontinuation of physical activity

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine), unless contraindicated, will be used for long-term management of myasthenia gravis [34, 55, F, R]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [64, 65]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of stiff-person syndrome [64, 65]

AND

2 - Trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [64, 65]

AND

3 - Trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [64, 65]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [64, 65]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam

- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Stiff Person Syndrome (off-label) [64, 65]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of stiff-person syndrome [64, 65]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [64, 65]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [64, 65]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 23, 47]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand

BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - One of the following diagnoses [23]:

- Dermatomyositis
- Polymyositis

AND

2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [23, Q]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 23, 47]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			

PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 23, 47]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - One of the following diagnoses [23]:

- Dermatomyositis
- Polymyositis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [23, Q]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [29, 80, 83]
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Patients with severe disease requiring aid to walk [80, E]

AND

3 - Onset of neuropathic symptoms within the last four weeks [80, E]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [29, 80, 83]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam

- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Guillain-Barre Syndrome (off-label) [29, 80, 83]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Patients with severe disease requiring aid to walk [80, E]

AND

3 - Onset of neuropathic symptoms within the last four weeks [80, E]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [84]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			

GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS)

AND

2 - History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [62, 63]

AND

3 - Concomitant immunomodulator therapy (eg, azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [62, 63]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam

- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [84]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand

ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Alyglo, Asceniv	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [84]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [62, 63]

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [62, 63]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name:Cytogam	
Diagnosis	Prophylaxis for CMV Infection
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CYTOGAM	CYTOMEGALOVIRUS IMMUNE GLOBULIN (HUMAN) IV INJ	19100005002020	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient requires prophylaxis for CMV infection following kidney transplantation

AND

1.1.2 Patient is CMV- seronegative and organ donor is CMV-seropositive

OR

1.2 All of the following:

1.2.1 Patient requires prophylaxis for CMV infection following liver, heart, lung, or pancreas transplantation

AND

1.2.2 Patient is CMV- seronegative and organ donor is CMV-seropositive

AND

1.2.3 Used in combination with ganciclovir or valganciclovir unless the patient has a hypersensitivity to, is intolerant of, or therapy is deemed inappropriate

Product Name:Varizig	
Diagnosis	Varicella
Approval Length	1 Dose
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VARIZIG	VARICELLA-ZOSTER IMMUNE GLOB (HUMAN) IM INJ 125 UNIT/1.2ML	19100070002015	Brand
VARIZIG	VARICELLA-ZOSTER IMMUNE GLOB (HUMAN) FOR IM INJ 125 UNIT	19100070002122	Brand
VARIZIG			

Approval Criteria

1 - For passive immunization or post exposure-prophylaxis of varicella

AND

2 - Patient is considered a high risk individual (e.g., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old)

AND

3 - Prescribed immune globulin is being used intramuscularly

Product Name:Intravenous immune globulin (IVIG)

Diagnosis	Pediatric Acute-Onset Neuropsychiatric Syndrome/Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANS/PANDAS) (off-label)
Approval Length	6 Month(s) [74]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMMAPLEX	IMMUNE GLOBULIN (HUMAN) IV SOLN 2.5 GM/50ML	19100020102034	Brand
GAMMAPLEX	IMMUNE GLOBULIN (HUMAN) IV SOLN 5 GM/100ML	19100020102038	Brand
GAMMAPLEX	IMMUNE GLOBULIN (HUMAN) IV SOLN 10 GM/200ML	19100020102042	Brand
FLEBOGAMMA DIF	IMMUNE GLOBULIN (HUMAN) IV SOLN 20 GM/400ML	19100020102044	Brand
BIVIGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 5 GM/50ML	19100020102068	Brand
PRIVIGEN	IMMUNE GLOBULIN (HUMAN) IV SOLN 10 GM/100ML	19100020102072	Brand
BIVIGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 10 GM/100ML	19100020102072	Brand
FLEBOGAMMA DIF	IMMUNE GLOBULIN (HUMAN) IV SOLN 10 GM/100ML	19100020102072	Brand
PRIVIGEN	IMMUNE GLOBULIN (HUMAN) IV SOLN 20 GM/200ML	19100020102076	Brand
FLEBOGAMMA DIF	IMMUNE GLOBULIN (HUMAN) IV SOLN 20 GM/200ML	19100020102076	Brand
GAMMAGARD S/D	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN 2.5 GM	19100020102115	Brand
GAMMAGARD S/D	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN 5 GM	19100020102120	Brand
GAMMAGARD S/D IGA LESS THAN 1MCG/ML	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN 5 GM	19100020102120	Brand
GAMMAGARD S/D	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN 10 GM	19100020102130	Brand
GAMMAGARD S/D IGA LESS THAN 1MCG/ML	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN 10 GM	19100020102130	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 1 GM/10ML	19100020302060	Brand
GAMUNEX-C	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 1 GM/10ML	19100020302060	Brand

GAMMAKED	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 1 GM/10ML	19100020302060	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 2.5 GM/25ML	19100020302064	Brand
GAMUNEX-C	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 2.5 GM/25ML	19100020302064	Brand
GAMMAKED	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 2.5 GM/25ML	19100020302064	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 5 GM/50ML	19100020302068	Brand
GAMUNEX-C	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 5 GM/50ML	19100020302068	Brand
GAMMAKED	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 5 GM/50ML	19100020302068	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 10 GM/100ML	19100020302072	Brand
GAMUNEX-C	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 10 GM/100ML	19100020302072	Brand
GAMMAKED	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 10 GM/100ML	19100020302072	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 20 GM/200ML	19100020302076	Brand
GAMUNEX-C	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 20 GM/200ML	19100020302076	Brand
GAMMAKED	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 20 GM/200ML	19100020302076	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 30 GM/300ML	19100020302080	Brand
OCTAGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 2 GM/20ML	19100020102063	Brand
OCTAGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 5 GM/50ML	19100020102068	Brand
OCTAGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 10 GM/100ML	19100020102072	Brand
OCTAGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 20 GM/200ML	19100020102076	Brand
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 1 GM/10ML	19100020602020	Brand
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 2.5 GM/25ML	19100020602025	Brand
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 5 GM/50ML	19100020602030	Brand
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 10 GM/100ML	19100020602035	Brand
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 20 GM/200ML	19100020602040	Brand

PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 30 GM/300ML	19100020602045	Brand
OCTAGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 30 GM/300ML	19100020102080	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)
- Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)

AND

2 - Disease is moderate to severe as defined by distressing symptoms that interfere with daily activities that occupy at least 50 percent (%) of waking hours [75]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [76]

- Corticosteroids (e.g., prednisone, dexamethasone, methylprednisolone)
- NSAIDs (e.g., Ibuprofen, naproxen, celecoxib)

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard

- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

3 . Endnotes

A. Guidelines from the British Committee for Standards in Haematology [11] and the National Comprehensive Cancer Network [16] state that IVIG therapy may be beneficial in patients with recurrent infections. Clinical studies show that IVIG reduces the number of bacterial infections, but not viral or fungal infections. [22]
B. Based on inclusion criteria from Molica et al. [14]
C. According to published data, there appears to be no difference in efficacy among IVIG, plasma exchange, and corticosteroids. [15, 16]
D. A controlled trial indicated that treatment with IVIG beyond three months was associated with a delayed recovery of humoral immunity, and the rate of infections after two years of treatment was increased significantly in IVIG recipients. [23] Centers for Disease Control and Prevention, Infectious Disease Society of America, and American Society of Blood and Marrow Transplantation guidelines recommended routine IVIG use to prevent bacterial infections among BMT recipients with unrelated marrow grafts who experience severe hypogammaglobulinemia (e.g., IgG < 400 mg/dl) within the first 100 days after transplant. [19]
E. The American Academy of Neurology recommends that IVIG is for patients with GBS who require aid to walk within 2 weeks from the onset of neuropathic symptoms. [80]
F. The effectiveness of IVIG for moderate-to-severe but stable myasthenia gravis, or for moderate exacerbations of myasthenia gravis have not been demonstrated in adequately controlled trials. [34] IVIG may be as effective as plasma exchange for patients with acute exacerbations of myasthenia gravis. The indications for the use of IVIG are the same as those for plasma exchange: to produce rapid improvement to help the patient through a difficult period of myasthenic weakness. It has the advantages of not requiring special equipment or large-bore vascular access. [42] The usual dose of immune globulin is 400 mg per kilogram per day for five successive days. The improvement rate after immune globulin treatment, calculated from eight published reports, was 73 percent, but this figure is likely to be biased by selective reporting of positive uncontrolled trials. In patients who respond, improvement begins within four to five days. The effect is temporary but may be sustained for weeks to months, allowing intermittent long-term therapy in patients with otherwise refractory disease.
G. Guidelines from the American Academy of Neurology [87] state that interferon Beta or glatirimer are appropriate treatments for patients who have relapsing-remitting multiple sclerosis. The guidelines state that it is only possible that IVIG reduces the attack rate in

RRMS, and that current evidence suggests IVIG is of little benefit with regard to slowing disease progression.

H. Treatment for CIDP includes corticosteroids such as prednisone, which may be prescribed alone or in combination with immunosuppressant drugs. [41] Plasmapheresis and intravenous immunoglobulin (IVIG) therapy are effective. IVIG may be used even as a first-line therapy. Physiotherapy may improve muscle strength, function and mobility, and minimize the shrinkage of muscles and tendons and distortions of the joints.
I. Subcutaneous formulations of immune globulin are available for the treatment of patients with primary immune deficiency. Subcutaneous infusions may be an alternative for patients with adverse effects to intravenous infusions of immune globulin or with poor venous access. Other advantages include decreased cost of administration, independence from scheduled home nursing visits, better maintenance of intravenous immune globulin trough levels, and a serum IgG profile (smaller variation in the peak and trough IgG concentrations compared to intravenous administration) that is similar to that in a normal population. Disadvantages include more frequent infusions and local reactions. [6]
J. There are good data to show that all immune globulins (IVIG/SCIG) are effective for primary immunodeficiency. There are no data for SCIG for indications other than PI. Efficacy is a class effect for all immune globulins products. It is appropriate to combine all IVIG/SCIG products as they are used interchangeably for PI; can combine all IVIG for other indications. Gamastan S/D (IMIG) has unique indications and should be available on the formulary. [85]
K. IVIG has been used in children with symptomatic human immunodeficiency virus (HIV) infection who are immunosuppressed in association with acquired immunodeficiency syndrome (AIDS) or AIDS-related complex (ARC) in an attempt to control or prevent infections and improve immunologic parameters. Results of studies in adults and children with symptomatic HIV infection indicate that IVIG, used in dosages similar to those used for replacement therapy in patients with primary immunodeficiencies, reduces the incidence of recurrent bacterial infections and sepsis, including upper respiratory tract infections. [86]
L. The ACIP, American Academy of Pediatrics (AAP), Centers for Disease Control (CDC), National Institutes of Health (NIH), HIV Medicine Association of the Infectious Diseases Society of America (IDSA), Pediatric Infectious Diseases Society, and other experts state that HIV-infected infants and children who have hypogammaglobulinemia (IgG less than 400 mg/dL) should receive IVIG (400 mg/kg once every 2-4 weeks) to prevent serious bacterial infections. [86]
M. Per expert consultant regarding MS: IVIG is only used in acute, severe MS. IVIG is used for bad relapses of MS with significant neurological dysfunction when a patient is breaking through their regular maintenance medications. It takes about 3 months to see if there is improvement in MS and one cannot say a patient has failed a medication if they have a breakthrough episode of MS within this 3 month period [67].
N. Per expert consultant regarding multifocal motor neuropathy: the European Federation of Neurological Societies (EFNS) guidelines [69] as outlined on page 344 and in the table are fairly reasonable: 1. Weakness with slowly progressive or stepwise progressive course 2. Asymmetric involvement of two or more nerves 3. Absence of upper motor neuron signs and bulbar signs [68].
O. Per expert consultant regarding MS: there are no data to support the initial length of IVIG treatment in MS. I would suggest 3 months and then reevaluate. An appropriate length of time for reauthorization of IVIG is 12 months. Patients who receive IVIG for RRMS should be in acute exacerbation, should have tried steroids, have documentation of inability to tolerate other disease modifying drugs, as well as show progression of

disease. IVIG should be used 2nd or 3rd line if other injectable disease modifying drugs are not tolerated. Guidelines do not support IVIG as first line treatment for MS [68].

P. Per expert consultant regarding CIDP: It is important to reevaluate a patient after initial treatment. Some patients may need changes in dosing intervals due to wearing off of a dose within 2-3 weeks. Treatment can be lifelong for some patient [68].
Q. Per expert consultant regarding dermatomyositis: It is reasonable to ask a patient to try steroids prior to treatment with IVIG. [68]
R. Per expert consultant regarding MG: IVIG should be used in patients with moderate to severe myasthenia gravis with acute exacerbation. Most MDs favor plasma exchange for maintenance therapy in MG patients. Myasthenic exacerbation = myasthenic crisis. [68]

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5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228439
Guideline Name	Inbrija (levodopa) inhalation powder
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Inbrija (levodopa inhalation powder)
Parkinson's Disease Indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa.

2 . Criteria

Product Name:Inbrija	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INBRIJA	LEVODOPA INHAL POWDER CAP 42 MG	73200040000160	Brand

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing intermittent OFF episodes

AND

3 - Patient is receiving Inbrija in combination with carbidopa/levodopa at a maximally tolerated dose

AND

4 - Trial and failure, contraindication or intolerance to two of the following: [A]

- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT Inhibitor (e.g., entacapone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Inbrija	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INBRIJA	LEVODOPA INHAL POWDER CAP 42 MG	73200040000160	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Patient is receiving Inbrija in combination with carbidopa/levodopa

3 . Endnotes

A. Primary treatment options for patients experiencing intermittent OFF episodes depends on the severity of the episodes. The easiest options include: shortening the dosing interval of levodopa, advising patient to take levodopa on an empty stomach if possible, or crushing the tablet and ingesting it with carbonated water for more predictable and faster absorption. Following the trial of the above options, entacapone, MAO-B Inhibtors or Dopamine Agonists may be added to the patient's therapy to enhance dopamine levels. [2]

4 . References

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Prior Authorization Guideline

Guideline ID	GL-229120
Guideline Name	Increlex (mecasermin [rDNA origin])
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	4/4/2006
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Increlex (mecasermin [rDNA origin]) injection
Severe Primary IGF-1 deficiency (Primary IGFD) Indicated for the treatment of growth failure in pediatric patients 2 years of age and older with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Severe Primary IGFD is defined by: height standard deviation score less than or equal to -3.0, basal IGF-1 standard deviation score less than or equal to -3.0, and normal or elevated GH. Limitations of use: Increlex is not a substitute to GH for approved GH indications. Increlex is not indicated for use in patients with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacological doses of anti-inflammatory corticosteroids.

2 . Criteria

Product Name:Increlex	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INCRELEX	MECASERMIN INJ 40 MG/4ML (10 MG/ML)	30160045002020	Brand

Approval Criteria

1 - One of the following: [A]

1.1 All of the following:

1.1.1 Diagnosis of severe primary IGF-1 deficiency [3]

AND

1.1.2 Height standard deviation score less than or equal to -3.0

AND

1.1.3 Basal IGF-1 standard deviation score less than or equal to -3.0

AND

1.1.4 Normal or elevated growth hormone

AND

1.1.5 Prescribed by or in consultation with a pediatric endocrinologist

OR

1.2 Both of the following:

1.2.1 Diagnosis of growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH

AND

1.2.2 Prescribed by or in consultation with a pediatric endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal. Increlex is not a substitute for GH for approved GH indications.

Product Name:Increlex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INCRELEX	MECASERMIN INJ 40 MG/4ML (10 MG/ML)	30160045002020	Brand

Approval Criteria

1 - Growth increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [2, B]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

• Expected adult height is not obtained • Documentation of expected adult height goal	
Notes	NOTE: Increlex is not a substitute for GH for approved GH indications.

3 . Endnotes

A. Growth Hormone Deficiency (GHD) and severe Primary IGF-1 Deficiency (IGFD) are two distinct hormone disorders. Patients with severe Primary IGFD are not GH deficient, and therefore, exogenous GH treatment cannot be expected to resolve the patient's growth deficiency. [1]
B. Typically near-adult height is defined as bone age of 16 years or more for males and 14 years or more for females and a growth rate less than 2 cm/year for 1 year. [2]

4 . References

1. Increlex Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. March 2024.
2. Mauras N, Attie KM, Reiter EO, Saenger P, Baptista J. High dose recombinant human growth hormone (GH) treatment of GH-deficient patients in puberty increases near-final height: a randomized, multicenter trial. Genentech, Inc., Cooperative Study Group. J Clin Endocrinol Metab. 2000;85(10):3653-60.
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5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228883
Guideline Name	Infliximab – PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Remicade (infliximab), Infliximab, Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Renflexis (Infliximab-abda)
Rheumatoid Arthritis (RA) Indicated in combination with methotrexate, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. **Psoriatic Arthritis (PsA)** Indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. **Plaque Psoriasis (PsO)** Indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. Therapy should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. **Ankylosing Spondylitis (AS)** Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

Crohn's Disease (CD) Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.

Pediatric Crohn's Disease Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis (UC) Indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Off Label Uses: Sarcoidosis Has been used for the treatment of refractory sarcoidosis. [5-7]

Drug Name: Zymfentra (infliximab-dyyb) SC injection

Crohn's Disease (CD) Indicated in adults for maintenance treatment of moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously.

Ulcerative Colitis (UC) Indicated in adults for maintenance treatment of moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously.

2 . Criteria

Product Name:Avsola, Inflectra	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Used in combination with methotrexate

Product Name:Avsola, Inflectra	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand

AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Avsola, Inflectra	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name:Avsola, Inflectra	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name:Avsola, Inflectra	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - One of the following [5]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [6]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Avsola, Inflectra	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to infliximab therapy as evidenced by ONE of the following [1, 5]

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Avsola, Inflectra	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

Product Name:Avsola, Inflectra	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 7]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name:Avsola, Inflectra	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - One of the following diagnoses:

- Moderately to severely active Crohn's disease
- Fistulizing Crohn's disease

AND

2 - One of the following [8, 9]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [8, 9]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

Product Name:Zymfentra	
Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Avsola, Inflectra, Zymfentra	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 8, 9]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Product Name:Zymfentra	
Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Submission of medical records (e.g., chart notes) confirming the provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Avsola, Inflectra	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [10, 11]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [10, 11]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

- Azathioprine
- Corticosteroids (e.g., prednisone)

Product Name:Zymfentra	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Avsola, Inflectra, Zymfentra	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 10, 11]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Product Name:Zymfentra	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Submission of medical records (e.g., chart notes) confirming the provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Avsola, Inflectra	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of sarcoidosis

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Dermatologist
- Ophthalmologist

AND

3 - Trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone)

AND

4 - Trial and failure, contraindication, or intolerance to one immunosuppressant (e.g., methotrexate, cyclophosphamide, or azathioprine)

Product Name:Avsola, Inflectra	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to infliximab therapy

Product Name:Remicade, Infliximab, Renflexis	
Approval Length	12 month(s)
Guideline Type	Prior Authorization, Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
REMICADE	INFLIXIMAB FOR IV INJ 100 MG	52505040002120	Brand
RENFLEXIS	INFLIXIMAB-ABDA FOR IV INJ 100 MG	52505040102120	Brand
INFLIXIMAB	INFLIXIMAB FOR IV INJ 100 MG	52505040002120	Brand

Approval Criteria

1 - Patient has one of the following diagnoses:

- Rheumatoid arthritis (RA)
- Psoriatic Arthritis (PsA)
- Plaque Psoriasis (PsO)

- Ankylosing Spondylitis (AS)
- Crohn's Disease (CD) or Fistulizing Crohn's Disease
- Ulcerative Colitis (UC)
- Sarcoidosis (off-label)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of BOTH of the following:

- Avsola
- Inflectra

AND

3 - Submission of medical records documenting why the covered products have not been effective

3 . References

1. Remicade Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 2021.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
6. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
7. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
8. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
9. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.

10. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
11. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.
12. DRUGDEX System [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed July 7, 2020.
13. Baughman RP, Drent M, Kavuru M, et al. Infliximab therapy in patients with chronic sarcoidosis and pulmonary involvement Am J Respir Crit Care Med. 2006 Oct 1;174(7):795-802.
14. Rossman M, Newman LS, Baughman RP, et al. A double-blinded, randomized, placebo-controlled trial of infliximab in subjects with active pulmonary sarcoidosis. Sarcoidosis Vasc Diffuse Lung Dis. 2006;23(3):201-8.
15. Per clinical consult with dermatologist. June 26, 2019.
16. Avsola Prescribing Information. Amgen Inc. Thousand Oaks, CA. September 2021.
17. Inflectra prescribing information. Hospira. Lake Forest, IL. March 2022.
18. Renflexis Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. December 2023.
19. Infliximab Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 2021.
20. Zymfentra Prescribing Information. Celltrion USA, Inc. Jersey City, NJ. February 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228666
Guideline Name	Ingrezza (valbenazine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ingrezza (valbenazine)
Tardive Dyskinesia Indicated for the treatment of adults with tardive dyskinesia. **Chorea associated with Huntington's disease** Indicated for the treatment of adults with chorea associated with Huntington’s disease

2 . Criteria

Product Name:Ingrezza	
Diagnosis	Tardive Dyskinesia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INGREZZA	VALBENAZINE TOSYLATE CAP 40 MG (BASE EQUIV)	62380080200120	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP 80 MG (BASE EQUIV)	62380080200140	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP THERAPY PACK 40 MG (7) & 80 MG (21)	6238008020B220	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP 60 MG (BASE EQUIV)	62380080200130	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 40 MG (BASE EQUIV)	62380080206830	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 60 MG (BASE EQUIV)	62380080206850	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 80 MG (BASE EQUIV)	62380080206870	Brand

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia [A]

AND

2 - One of the following [3, B]:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist

- Psychiatrist

Product Name:Ingrezza	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INGREZZA	VALBENAZINE TOSYLATE CAP 40 MG (BASE EQUIV)	62380080200120	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP 80 MG (BASE EQUIV)	62380080200140	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP THERAPY PACK 40 MG (7) & 80 MG (21)	6238008020B220	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP 60 MG (BASE EQUIV)	62380080200130	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 40 MG (BASE EQUIV)	62380080206830	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 60 MG (BASE EQUIV)	62380080206850	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 80 MG (BASE EQUIV)	62380080206870	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Ingrezza	
Diagnosis	Chorea Associated with Huntington’s Disease
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INGREZZA	VALBENAZINE TOSYLATE CAP 40 MG (BASE EQUIV)	62380080200120	Brand

INGREZZA	VALBENAZINE TOSYLATE CAP 80 MG (BASE EQUIV)	62380080200140	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP THERAPY PACK 40 MG (7) & 80 MG (21)	6238008020B220	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP 60 MG (BASE EQUIV)	62380080200130	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 40 MG (BASE EQUIV)	62380080206830	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 60 MG (BASE EQUIV)	62380080206850	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 80 MG (BASE EQUIV)	62380080206870	Brand

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

AND

2 - Prescribed by or in consultation with a neurologist

Product Name:Ingrezza	
Diagnosis	Chorea Associated with Huntington’s Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INGREZZA	VALBENAZINE TOSYLATE CAP 40 MG (BASE EQUIV)	62380080200120	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP 80 MG (BASE EQUIV)	62380080200140	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP THERAPY PACK 40 MG (7) & 80 MG (21)	6238008020B220	Brand
INGREZZA	VALBENAZINE TOSYLATE CAP 60 MG (BASE EQUIV)	62380080200130	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 40 MG (BASE EQUIV)	62380080206830	Brand
INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 60 MG (BASE EQUIV)	62380080206850	Brand

INGREZZA	VALBENAZINE TOSYLATE CAPSULE SPRINKLE 80 MG (BASE EQUIV)	62380080206870	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. Patients were included in the pivotal randomized, double-blind, placebo-controlled trial of Ingrezza if they had moderate to severe tardive dyskinesia as determined by clinical observation (qualitative assessment). [1, 2]
B. Verified with consultant that dose reduction, tapering, or discontinuation of the offending medication is considered first-line treatment for tardive dyskinesia. [4]

4 . References

1. Ingrezza Prescribing Information. Neurocrine Biosciences, Inc. San Diego, CA. April 2024.
2. Hauser RA, Factor SA, Marder SR, et al. KINECT 3: A phase 3 randomized, double-blind, placebo-controlled trial of valbenazine for tardive dyskinesia. Am J Psychiatry. 2017 May 1;174(5):476-484.
3. Waln O, Jankovic J. An update on tardive dyskinesia: from phenomenology to treatment. Tremor Other Hyperkinet Mov (N Y) 2013 Jul 12;3. pii: tre-03-161-4138-1.
4. Per clinical consult with psychiatrist, June 9, 2017.

Prior Authorization Guideline

Guideline ID	GL-228885
Guideline Name	Inhaled Corticosteroids - ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Alvesco (ciclesonide) Inhalation Aerosol
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older. Important Limitations of Use: Alvesco is NOT indicated for the relief of acute bronchospasm or for children under 12 years of age.
Drug Name: ArmonAir Digihaler (fluticasone propionate) Inhalation Powder
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Limitations of Use: ArmonAir Digihaler is not indicated for the relief of acute bronchospasm.
Drug Name: Asmanex HFA (mometasone furoate) Inhalation Aerosol
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. Important Limitations of Use: Asmanex HFA is NOT indicated for the relief of acute bronchospasm.
Drug Name: Asmanex (mometasone furoate) Inhalation Powder

Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older. Limitations of Use: Asmanex Twisthaler is NOT indicated for the relief of acute bronchospasm or in children less than 4 years of age.
Drug Name: Flovent (fluticasone propionate aerosol) HFA
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients aged 4 years and older. Limitations of Use FLOVENT HFA is not indicated for the relief of acute bronchospasm.
Drug Name: Flovent (fluticasone propionate powder) Diskus
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients aged 4 years and older. Important Limitation of Use FLOVENT DISKUS is NOT indicated for the relief of acute bronchospasm.
Drug Name: Pulmicort (budesonide aerosol) Flexhaler
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients six years of age or older. Limitations of Use: PULMICORT FLEXHALER is NOT indicated for the relief of acute bronchospasm.

2 . Criteria

Product Name:Armonair Digihaler*, Asmanex Twisthaler*, Flovent Diskus, Pulmicort Flexhaler, Brand Fluticasone Propionate Diskus	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ASMANEX TWISTHALER 30 METERED DOSES	MOMETASONE FUROATE INHAL POWD 110 MCG/INH (BREATH ACTIVATED)	44400036208010	Brand
ASMANEX TWISTHALER 120 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand
ASMANEX TWISTHALER 60 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand

ASMANEX TWISTHALER 14 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand
ASMANEX TWISTHALER 30 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand
ASMANEX 14 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand
ASMANEX TWISTHALER 30 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Generic
ASMANEX TWISTHALER 14 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Generic
ASMANEX TWISTHALER 60 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Generic
ASMANEX TWISTHALER 120 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Generic
ARMONAIR DIGIHALER	FLUTICASONE PROPIONATE AER POW BA 55 MCG/ACT WITH SENSOR	44400033218020	Brand
ARMONAIR DIGIHALER	FLUTICASONE PROPIONATE AER POW BA 113 MCG/ACT WITH SENSOR	44400033218030	Brand
ARMONAIR DIGIHALER	FLUTICASONE PROPIONATE AER POW BA 232 MCG/ACT WITH SENSOR	44400033218040	Brand
FLOVENT DISKUS	FLUTICASONE PROPIONATE AER POW BA 50 MCG/ACT	44400033208010	Brand
FLOVENT DISKUS	FLUTICASONE PROPIONATE AER POW BA 100 MCG/ACT	44400033208020	Brand
FLOVENT DISKUS	FLUTICASONE PROPIONATE AER POW BA 250 MCG/ACT	44400033208030	Brand
PULMICORT FLEXHALER	BUDESONIDE INHAL AERO POWD 90 MCG/ACT (BREATH ACTIVATED)	44400015008009	Generic
PULMICORT FLEXHALER	BUDESONIDE INHAL AERO POWD 180 MCG/ACT (BREATH ACTIVATED)	44400015008018	Generic
FLUTICASONE PROPIONATE DISKUS	FLUTICASONE PROPIONATE AER POW BA 50 MCG/ACT	44400033208010	Generic
FLUTICASONE PROPIONATE DISKUS	FLUTICASONE PROPIONATE AER POW BA 100 MCG/ACT	44400033208020	Generic

FLUTICASONE PROPIONATE DISKUS	FLUTICASONE PROPIONATE AER POW BA 250 MCG/ACT	44400033208030	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to both of the following preferred brands:

- Arnuity Ellipta
- QVAR Redihaler

Notes	*Product may be excluded depending on the plan.

Product Name:Flovent HFA, Brand Fluticasone Propionate HFA, Alvesco*, Asmanex HFA*	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ALVESCO	CICLESONIDE INHAL AEROSOL 80 MCG/ACT	44400017003420	Brand
ALVESCO	CICLESONIDE INHAL AEROSOL 160 MCG/ACT	44400017003440	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 50 MCG/ACT	44400036203210	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 100 MCG/ACT	44400036203220	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 200 MCG/ACT	44400036203230	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AERO 44 MCG/ACT (50/VALVE)	44400033223220	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AER 110 MCG/ACT (125/VALVE)	44400033223230	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AER 220 MCG/ACT (250/VALVE)	44400033223240	Generic

FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AERO 44 MCG/ACT (50/VALVE)	44400033223220	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AER 110 MCG/ACT (125/VALVE)	44400033223230	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AER 220 MCG/ACT (250/VALVE)	44400033223240	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 50 MCG/ACT	44400036203210	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 100 MCG/ACT	44400036203220	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 200 MCG/ACT	44400036203230	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to both of the following preferred brands:

- Arnuity Ellipta
- QVAR Redihaler

OR

2.2 Submission of medical records (e.g., chart notes) confirming patient requires a metered dose inhaler used with a spacer device due to one of the following:

- Physical dexterity
- Inspiratory flow
- Cognitive status

Notes	*Product may be excluded depending on the plan.

Product Name:Flovent HFA, Brand Fluticasone Propionate HFA, Alvesco, Asmanex HFA	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ALVESCO	CICLESONIDE INHAL AEROSOL 80 MCG/ACT	44400017003420	Brand
ALVESCO	CICLESONIDE INHAL AEROSOL 160 MCG/ACT	44400017003440	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 50 MCG/ACT	44400036203210	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 100 MCG/ACT	44400036203220	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 200 MCG/ACT	44400036203230	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AERO 44 MCG/ACT (50/VALVE)	44400033223220	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AER 110 MCG/ACT (125/VALVE)	44400033223230	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AER 220 MCG/ACT (250/VALVE)	44400033223240	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AERO 44 MCG/ACT (50/VALVE)	44400033223220	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AER 110 MCG/ACT (125/VALVE)	44400033223230	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AER 220 MCG/ACT (250/VALVE)	44400033223240	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 50 MCG/ACT	44400036203210	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 100 MCG/ACT	44400036203220	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 200 MCG/ACT	44400036203230	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - One of the following:

2.1 Submission of medical records (e.g., chart notes) confirming patient requires a metered dose inhaler used with a spacer device due to one of the following: [A, 9]

- Physical dexterity
- Inspiratory flow
- Cognitive status

OR

2.2 Submission of medical records (e.g., chart notes) or paid claims documenting patient has tried and failed, or has contraindication or intolerance to at least 3 formulary alternatives. If only 1 or only 2 alternatives are available, the patient must have failed or had contraindications or intolerance to all available formulary alternatives

3 . Endnotes

A. Dry powder inhalers are not suitable for those unable to use breath activated devices, such as young children or some elderly patients; pressurized metered dose inhalers with spacers remain essential for such patients. [9]

4 . References

1. Alvesco [prescribing information]. Zug 6300, Switzerland: Covis Pharma; February 2023.
2. ArmonAir Digihaler [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.
3. Asmanex [prescribing information]. Jersey City, NJ: Organon LLC; June 2021.
4. Asmanex HFA [prescribing information]. Jersey City, NJ: Organon LLC; March 2023.
5. Flovent HFA Prescribing Information. GlaxoSmithKline. Durham, NC. September 2023.
6. Flovent Diskus Prescribing Information. GlaxoSmithKline. Durham, NC. August 2023.
7. Pulmicort Flexhaler Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington DE. October 2019.
8. Fluticasone Propionate Diskus Prescribing Information. Prasco Laboratories Mason OH. May 2023.
9. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention 2023. Updated July 2023. Available from www.ginaasthma.org

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228889
Guideline Name	Inlyta (axitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Inlyta (axitinib)
Advanced Renal Cell Carcinoma Indicated in combination with avelumab or pembrolizumab, for the first-line treatment of patients with advanced renal cell carcinoma (RCC). It is also indicated as a single agent, for the treatment of advanced RCC after failure of one prior systemic therapy.

2 . Criteria

Product Name:Inlyta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INLYTA	AXITINIB TAB 1 MG	21335013000320	Brand
INLYTA	AXITINIB TAB 5 MG	21335013000340	Brand

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following:

2.1 Used as first-line treatment in combination with one of the following for clear cell renal cell carcinoma**: [2]

- avelumab*
- pembrolizumab*

OR

2.2 Used after failure of one prior systemic therapy (e.g., chemotherapy) for clear cell renal cell carcinoma** [2]

OR

2.3 One of the following:

2.3.1 Both of the following: [2]

- Used in the treatment of non-clear cell renal cell carcinoma
- Trial and failure, contraindication or intolerance to generic sunitinib

OR

2.3.2 For continuation of prior therapy

Notes	*This product may require prior authorization. ***Criterion is part of FDA-approved label

Product Name:Inlyta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INLYTA	AXITINIB TAB 1 MG	21335013000320	Brand
INLYTA	AXITINIB TAB 5 MG	21335013000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Inlyta Prescribing Information. Pfizer Labs. New York, NY. July 2024.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. v.1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed July 30, 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228891
Guideline Name	Inqovi (decitabine and cedazuridine) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Inqovi (decitabine and cedazuridine)
Myelodysplastic Syndromes (MDS) Indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

2 . Criteria

Product Name:Inqovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INQOVI	DECITABINE-CEDAZURIDINE TAB 35-100 MG	21990002250320	Brand

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

Product Name:Inqovi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INQOVI	DECITABINE-CEDAZURIDINE TAB 35-100 MG	21990002250320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Inqovi	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
INQOVI	DECITABINE-CEDAZURIDINE TAB 35-100 MG	21990002250320	Brand

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

3 . References

1. Inqovi prescribing information. Taiho Oncology, Inc. Princeton, NY. March 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228668
Guideline Name	Inrebic (fedratinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Inrebic (fedratinib)
Myelofibrosis Indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

2 . Criteria

Product Name:Inrebic	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INREBIC	FEDRATINIB HCL CAP 100 MG	21537520200120	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

Product Name:Inrebic	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INREBIC	FEDRATINIB HCL CAP 100 MG	21537520200120	Brand

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., symptom improvement, spleen volume reduction)

3 . References

1. Inrebic Prescribing Information. Celgene Corporation. Summit, NJ. July 2024.

Prior Authorization Guideline

Guideline ID	GL-228890
Guideline Name	Insomnia Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Edluar (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. The clinical trials performed with zolpidem tartrate in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.
Drug Name: Ambien (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.
Drug Name: Ambien CR (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Quviviq (daridorexant)

Insomnia Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance in adults.
Drug Name: Belsomra (suvorexant)
Insomnia Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Dayvigo (lemborexant)
Insomnia Indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Zolpidem tartrate capsule
Insomnia Indicated for the short-term treatment of transient insomnia characterized by difficulties with sleep initiation in adults younger than 65 years of age.

2 . Criteria

Product Name:Ambien, Ambien CR, Brand Zolpidem capsules, Edluar	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
EDLUAR	ZOLPIDEM TARTRATE SL TAB 5 MG	60204080100720	Brand
EDLUAR	ZOLPIDEM TARTRATE SL TAB 10 MG	60204080100730	Brand
AMBIEN	ZOLPIDEM TARTRATE TAB 5 MG	60204080100310	Brand
AMBIEN	ZOLPIDEM TARTRATE TAB 10 MG	60204080100315	Brand
AMBIEN CR	ZOLPIDEM TARTRATE TAB ER 6.25 MG	60204080100410	Brand
AMBIEN CR	ZOLPIDEM TARTRATE TAB ER 12.5 MG	60204080100420	Brand
ZOLPIDEM TARTRATE	ZOLPIDEM TARTRATE CAP 7.5 MG	60204080100120	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), or intolerance to one of the following:

- zolpidem
- zolpidem ER

Product Name:Quviviq	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
QUVIVIQ	DARIDOREXANT HCL TAB 25 MG	60500020100320	Brand
QUVIVIQ	DARIDOREXANT HCL TAB 50 MG	60500020100340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - ONE of the following:

2.1 If the patient is less than 65 years of age, BOTH of the following:

2.1.1 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to ONE of the following:

- Belsomra*
- Dayvigo*

AND

2.1.2 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to TWO of the following:

- eszopiclone
- zaleplon
- zolpidem
- zolpidem ER
- triazolam
- temazepam
- generic ramelteon
- doxepin

OR

2.2 If the patient is 65 years of age and older, trial and failure (of a minimum 30-day supply), contraindication, or intolerance to TWO of the following:

- generic ramelteon
- Belsomra*
- Dayvigo*
- doxepin

Notes	*NOTE: Step Therapy (ST) requirements may apply for brand Belsomra and brand Dayvigo

Product Name:Belsomra, Dayvigo	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
BELSOMRA	SUVOREXANT TAB 5 MG	60500070000305	Brand
BELSOMRA	SUVOREXANT TAB 10 MG	60500070000310	Brand
BELSOMRA	SUVOREXANT TAB 15 MG	60500070000315	Brand
BELSOMRA	SUVOREXANT TAB 20 MG	60500070000320	Brand
DAYVIGO	LEMBOREXANT TAB 5 MG	60500040000320	Brand
DAYVIGO	LEMBOREXANT TAB 10 MG	60500040000340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to one of the following:

- doxepin
- eszopiclone
- temazepam
- zaleplon
- zolpidem
- zolpidem ER

3 . References

1. Edluar Prescribing Information. Meda Pharmaceuticals Inc. Somerset, NJ. August 2022.
2. Ambien Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. February 2022.
3. Ambien CR Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. February 2022.
4. Quviviq Prescribing Information. Idorsia Pharmaceuticals US Inc. Radnor, PA. April 2023.
5. Belsomra Prescribing Information. Merck Sharp & Dohme LLC. Rahway, NJ. February 2023.
6. Dayvigo Prescribing Information. Eisai Inc. Nutley, NJ. May 2023.
7. The 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc 00:1-21, 2019. Available at https://www.uclahealth.org/geriatrics/workfiles/education/clinical-skills/handouts/Education-Updated-Beers-List-2019.pdf. Accessed August 7, 2023.
8. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: An American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(2):307-349. Available at https://jcsm.aasm.org/doi/10.5664/jcsm.6470. Accessed August 7, 2023.
9. UpToDate. Overview of the Treatment of Insomnia in Adults. Available at https://www.uptodate.com/contents/overview-of-the-treatment-of-insomnia-in-adults?search=insomnia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed August 7, 2023.

10. Zolpidem Prescribing Information. Almatica Pharma LLC. Morristown, NJ. May 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228892
Guideline Name	Insulin Delivery Systems
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Insulin dosers, cartridges, or pen devices			
Guideline Type	Administrative		

Product Name	Generic Name	GPI	Brand/Generic
Insulin			
Delivery			
System			
pen			
doser			
cartridge			

Approval Criteria

1 - Will be approved, except when excluded as a plan benefit, based on one of the following criteria:

1.1 The patient has visual impairment (unable to use insulin vial and syringe)

OR

1.2 The patient has physical impairment (unable to use insulin vial and syringe)

2 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229122
Guideline Name	Interstitial Lung Disease (ILD) Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/4/2014
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Esbriet (pirfenidone)
Idiopathic Pulmonary Fibrosis Indicated for the treatment of idiopathic pulmonary fibrosis (IPF).
Drug Name: Ofev (nintedanib)
Idiopathic Pulmonary Fibrosis Indicated for the treatment of adults with idiopathic pulmonary fibrosis (IPF). **Systemic Sclerosis-associated Interstitial Lung Disease** Indicated to slow the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD). **Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype**

Indicated for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.

2 . Criteria

Product Name:Brand Esbriet, Generic pirfenidone, Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis (IPF)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ESBRIET	PIRFENIDONE CAP 267 MG	45550060000120	Brand
OFEV	NINTEDANIB ESYLATE CAP 100 MG (BASE EQUIVALENT)	45554050200120	Brand
OFEV	NINTEDANIB ESYLATE CAP 150 MG (BASE EQUIVALENT)	45554050200130	Brand
ESBRIET	PIRFENIDONE TAB 267 MG	45550060000325	Brand
ESBRIET	PIRFENIDONE TAB 801 MG	45550060000345	Brand
PIRFENIDONE	PIRFENIDONE TAB 267 MG	45550060000325	Generic
PIRFENIDONE	PIRFENIDONE TAB 801 MG	45550060000345	Generic
PIRFENIDONE	PIRFENIDONE TAB 534 MG	45550060000333	Generic
PIRFENIDONE	PIRFENIDONE CAP 267 MG	45550060000120	Generic

Approval Criteria

1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by both of the following: [3]

1.1 Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity)

AND

1.2 One of the following:

1.2.1 In patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF

AND

2 - For brand Esbriet capsules and tablets, trial and failure or intolerance to generic pirfenidone

AND

3 - Prescribed by or in consultation with a pulmonologist

Product Name:Ofev	
Diagnosis	Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OFEV	NINTEDANIB ESYLATE CAP 100 MG (BASE EQUIVALENT)	45554050200120	Brand
OFEV	NINTEDANIB ESYLATE CAP 150 MG (BASE EQUIVALENT)	45554050200130	Brand

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following: [5-6]

1.1 Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity)

AND

1.2 One of the following:

1.2.1 In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD

AND

2 - Prescribed by or in consultation with a pulmonologist

Product Name:Ofev	
Diagnosis	Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OFEV	NINTEDANIB ESYLATE CAP 100 MG (BASE EQUIVALENT)	45554050200120	Brand
OFEV	NINTEDANIB ESYLATE CAP 150 MG (BASE EQUIVALENT)	45554050200130	Brand

Approval Criteria

1 - Diagnosis of chronic fibrosing interstitial lung disease

AND

2 - Patient has a high-resolution computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features

AND

3 - Disease has a progressive phenotype as observed by one of the following:

- Decline of forced vital capacity (FVC)
- Worsening of respiratory symptoms
- Increased extent of fibrosis seen on imaging

AND

4 - Prescribed by or in consultation with a pulmonologist

Product Name:Brand Esbriet, Generic pirfenidone	
Diagnosis	Idiopathic Pulmonary Fibrosis (IPF)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ESBRIET	PIRFENIDONE CAP 267 MG	45550060000120	Brand
ESBRIET	PIRFENIDONE TAB 267 MG	45550060000325	Brand
ESBRIET	PIRFENIDONE TAB 801 MG	45550060000345	Brand
PIRFENIDONE	PIRFENIDONE TAB 267 MG	45550060000325	Generic

PIRFENIDONE	PIRFENIDONE TAB 801 MG	45550060000345	Generic
PIRFENIDONE	PIRFENIDONE TAB 534 MG	45550060000333	Generic
PIRFENIDONE	PIRFENIDONE CAP 267 MG	45550060000120	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - For brand Esbriet capsules and tablets, trial and failure or intolerance to generic pirfenidone

Product Name:Ofev	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OFEV	NINTEDANIB ESYLATE CAP 100 MG (BASE EQUIVALENT)	45554050200120	Brand
OFEV	NINTEDANIB ESYLATE CAP 150 MG (BASE EQUIVALENT)	45554050200130	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Esbriet prescribing information. Genentech, Inc. South San Francisco, CA. February 2023.
2. Ofev prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2024.

3. Raghu G, Collard HR, Egan JJ, et al. Official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. Am J of Respir Crit Care Med. 2011;183:788-824.
4. Raghu G, Rochwerg B, Zhang Y, et al. An Official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis, an update of the 2011 clinical practice guideline. Am J Respir Crit Care Med. 2015;192(2):e3-e19.
5. Fischer A, Swigris JJ, Groshong SD, et al. Clinically significant interstitial lung disease in limited scleroderma: histopathology, clinical features, and survival. Chest 2008; 134:601.
6. UptoDate [internet database]. Waltham, MA. UpToDate, Inc. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Available by subscription at: https://www.uptodate.com. Accessed November 18, 2020.
7. Pirfenidone Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, New Jersey. March 2023.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Iqirvo (elafibranor)

Prior Authorization Guideline

Guideline ID	GL-233283
Guideline Name	Iqirvo (elafibranor)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	8/15/2024
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Iqirvo (elafibranor)
Primary biliary cholangitis (PBC) Indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. This indication is approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Limitations of Use: Use of Iqirvo is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)

2 . Criteria

Product Name:Iqirvo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IQIRVO	ELAFIBRANOR TAB 80 MG	52780020000320	Brand

Approval Criteria

1 - Diagnosis of primary biliary cholangitis (PBC) (also known as primary biliary cirrhosis)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after at least 12 consecutive months of treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) [2, A]

AND

2.1.2 Used in combination with ursodeoxycholic acid (UDCA)

OR

2.2 History of contraindication or intolerance to ursodeoxycholic acid (UDCA)

AND

3 - Requested drug will not be used in combination with Ocaliva (obeticholic acid) or Livdelzi (seladelpar)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

Product Name:Iqirvo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IQIRVO	ELAFIBRANOR TAB 80 MG	52780020000320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., ALP level less than 1.67 times ULN, total bilirubin less than or equal to ULN, ALP decrease greater than or equal to 15% from baseline)

AND

2 - Requested drug will not be used in combination with Ocaliva (obeticholic acid) or Livdelzi (seladelpar)

3 . Endnotes

A. Biochemical response should be assessed after 1 year of treatment with UDCA [2]

4 . References

1. Iqirvo Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. June 2024.
2. Lindor, Keith D.*,1; Bowlus, Christopher L.2; Boyer, James3; Levy, Cynthia4; Mayo, Marlyn5. Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. Hepatology 69(1):p 394-419, January 2019. | DOI: 10.1002/hep.30145

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228442
Guideline Name	Iressa (gefitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Iressa (gefitinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Limitation of Use: Safety and efficacy of Iressa have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

2 . Criteria

Product Name:Brand Iressa, Generic gefitinib	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IRESSA	GEFITINIB TAB 250 MG	21360030000320	Brand
GEFITINIB	GEFITINIB TAB 250 MG	21360030000320	Generic

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Trial and failure, or intolerance to generic gefitinib (Applies to Brand Iressa only)

Product Name:Brand Iressa, Generic gefitinib	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IRESSA	GEFITINIB TAB 250 MG	21360030000320	Brand
GEFITINIB	GEFITINIB TAB 250 MG	21360030000320	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure, or intolerance to generic gefitinib (Applies to Brand Iressa only)

3 . References

1. Iressa Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. February 2023.
2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc.; 2014. Updated periodically. Available by subscription at: www.nccn.org. Accessed March 27, 2023.

Prior Authorization Guideline

Guideline ID	GL-228444
Guideline Name	Iron Products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Accrufer (ferric maltol)
Iron deficiency Indicated for the treatment of iron deficiency in adults
Drug Name: Feraheme (ferumoxytol injection)
Iron deficiency Indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have chronic kidney disease (CKD).
Drug Name: Injectafer (ferric carboxymaltose injection)
Iron Deficiency Anemia Indicated for the treatment of iron deficiency anemia (IDA) in adult and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron or adult patients who have non-dialysis dependent chronic kidney disease (CKD). **Iron deficiency** Indicated for the treatment of iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.

Drug Name: Monoferric (ferric derisomaltose injection)
Iron deficiency Indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have non-hemodialysis dependent chronic kidney disease (CKD).

2 . Criteria

Product Name:Accrufer, Brand Feraheme, generic ferumoxytol, Monoferric	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ACCRUFER	FERRIC MALTOL CAP 30 MG (FE EQUIV)	82300063000120	Brand
MONOFERRIC	FERRIC DERISOMALTOSE (ONE DOSE) IV SOL 1000 MG/10ML (FE EQ)	82300061002030	Brand
FERAHEME	FERUMOXYTOL INJ 510 MG/17ML (30 MG/ML) (ELEMENTAL FE)	82300068002020	Brand
FERUMOXYTOL	FERUMOXYTOL INJ 510 MG/17ML (30 MG/ML) (ELEMENTAL FE)	82300068002020	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 30-day supply or intolerance to one of the following generics:

- ferrous sulfate
- ferrous gluconate
- ferrous fumarate

Product Name:Injectafer	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
INJECTAFER	FERRIC CARBOXYMALTOSE IV SOLN 750 MG/15ML (FE EQUIVALENT)	82300062002030	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Trial and failure of a minimum 30-day supply or intolerance to one of the following generics:

- ferrous sulfate
- ferrous gluconate
- ferrous fumarate

OR

2.2 Patient has New York Heart Association class II or III Heart Failure [A]

3 . Endnotes

A. 2022 ACC/AHA guidelines note that oral iron supplementation is not adequate to treat iron deficiency anemia in patients with heart failure so having patients try oral iron supplementation is not clinically appropriate. In patients with heart failure with reduced ejection fraction and iron deficiency with or without anemia, IV iron replacement is reasonable to improve functional status and quality of life. Oral iron supplementation did not demonstrate the same effective compared to IV formulations. [5]

4 . References

1. Accrufer Prescribing Information. Shield Therapeutics Inc. October 2023.
2. Feraheme Prescribing Information. AMAG Pharmaceuticals, Inc. Waltham, MA. June 2022.
3. Injectafer Prescribing Information. American Regent, Inc. Shirley, NY. May 2023.
4. Monoferric Prescribing Information. Pharmacosmos Therapeutics, Inc. Morristown, NJ. February 2022.
5. Heidenreich, P. A., Bozkurt, B., Aguilar, D., Allen, L. A., Byun, J. J., Colvin, M. M., Deswal, A., Drazner, M. H., Dunlay, S. M., Evers, L. R., Fang, J. C., Fedson, S. E., Fonarow, G. C., Hayek, S. S., Hernandez, A. F., Khazanie, P., Kittleson, M. M., Lee, C. S., Link, M. S., Milano, C. A., … Yancy, C. W. (2022). 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation, 145(18), e876–e894.

Prior Authorization Guideline

Guideline ID	GL-228669
Guideline Name	Isotretinoin
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Absorica, Absorica LD
Severe recalcitrant nodular acne Indicated for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older. Nodules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhagic. “Severe,” by definition, means “many” as opposed to “few or several” nodules. Because of significant adverse reactions associated with its use, isotretinoin should be reserved for patients with multiple severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. In addition, isotretinoin is indicated only for those female patients who are not pregnant, because isotreinoin can cause severe birth defects. Limitations of Use: A single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy is needed, it should not be initiated until at least 8 weeks after completion of the first course, because experience with isotretinoin has shown that patients may continue to improve following treatment with isotretinoin. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth.

2 . Criteria

Product Name:Brand Absorica, Absorica LD	
Approval Length	5 Months [1-4, 10]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ABSORICA	ISOTRETINOIN CAP 10 MG	90050013000110	Brand
ABSORICA	ISOTRETINOIN CAP 20 MG	90050013000120	Brand
ABSORICA	ISOTRETINOIN CAP 25 MG	90050013000125	Brand
ABSORICA	ISOTRETINOIN CAP 30 MG	90050013000130	Brand
ABSORICA	ISOTRETINOIN CAP 35 MG	90050013000135	Brand
ABSORICA	ISOTRETINOIN CAP 40 MG	90050013000140	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 8 MG	90050013100110	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 16 MG	90050013100115	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 24 MG	90050013100125	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 32 MG	90050013100135	Brand

Approval Criteria

1 - Diagnosis of acne [1, 6-7, D]

AND

2 - One of the following:

2.1 Prescribed by a dermatologist

OR

2.2 Trial and failure, contraindication, or intolerance to an adequate trial (at least 6 weeks) on both of the following conventional therapy regimens:

2.2.1 One topical retinoid or retinoid-like agent [e.g., Retin-A/Retin-A Micro (tretinoin)] [2,4]

AND

2.2.2 Combination therapy with benzoyl peroxide and one of the following: [2-5]

2.2.2.1 Oral antibiotic [e.g., Ery-Tab (erythromycin), Minocin (minocycline)] [1, 4, A]

OR

2.2.2.2 If oral antibiotics are not indicated, a topical antibiotic [e.g., Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)] [2-4]

Product Name:Brand Absorica, Absorica LD	
Diagnosis	Persistent or Recurring Acne After 2 Months Off Therapy
Approval Length	5 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ABSORICA	ISOTRETINOIN CAP 10 MG	90050013000110	Brand
ABSORICA	ISOTRETINOIN CAP 20 MG	90050013000120	Brand
ABSORICA	ISOTRETINOIN CAP 25 MG	90050013000125	Brand
ABSORICA	ISOTRETINOIN CAP 30 MG	90050013000130	Brand
ABSORICA	ISOTRETINOIN CAP 35 MG	90050013000135	Brand
ABSORICA	ISOTRETINOIN CAP 40 MG	90050013000140	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 8 MG	90050013100110	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 16 MG	90050013100115	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 24 MG	90050013100125	Brand

ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 32 MG	90050013100135	Brand

Approval Criteria

1 - After more than 2 months off therapy, persistent or recurring acne is still present [1, 6-7, B, D]

Notes	Authorization will be given only by clinical pharmacist review for up to 5 months.

Product Name:Brand Absorica, Absorica LD	
Diagnosis	Dose Titration
Approval Length	1 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ABSORICA	ISOTRETINOIN CAP 10 MG	90050013000110	Brand
ABSORICA	ISOTRETINOIN CAP 20 MG	90050013000120	Brand
ABSORICA	ISOTRETINOIN CAP 30 MG	90050013000130	Brand
ABSORICA	ISOTRETINOIN CAP 40 MG	90050013000140	Brand
ABSORICA	ISOTRETINOIN CAP 25 MG	90050013000125	Brand
ABSORICA	ISOTRETINOIN CAP 35 MG	90050013000135	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 8 MG	90050013100110	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 16 MG	90050013100115	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 24 MG	90050013100125	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 32 MG	90050013100135	Brand

Approval Criteria

1 - Confirmation that the cumulative dose is less than 150 mg/kg (there is little therapeutic benefit to be gained by increasing the cumulative dose beyond 150 mg/kg) [1, 6, C]*

Notes	Authorization will be given only by clinical pharmacist review for 1 mo nth to allow for titration up to target dose within a treatment cycle (20 weeks). *See background section for dosing regimens

3 . Background

Benefit/Coverage/Program Information

Dosing by Body Weight (based on administration with food):

Body Weight		Daily Dose		
Kg	Lbs	0.5 mg/kg/day	1 mg/kg/day	2 mg/kg/day
40	88	20	40	80
50	110	25	50	100
60	132	30	60	120
70	154	35	70	140
80	176	40	80	160
90	198	45	90	180
100	220	50	100	200

4 . Endnotes

A. Isotretinoin use has been associated with a number of cases of pseudotumor cerebri (benign intracranial hypertension), some of which involved concomitant use of tetracyclines. Concomitant treatment with tetracyclines should therefore be avoided. [1]
B. Experience has shown that patients may continue to improve while off isotretinoin therapy. After a period of 2 months or more 'off therapy', and if warranted by persistent or recurring severe nodular acne, a second course of therapy of isotretinoin may be initiated. [1]
C. According to the AAD, acne experts feel strongly that initial flaring can be decreased with a beginning dose of 0.5 mg/kg/day or less. Lower doses can be used for longer periods of time with a total cumulative dose of 120 to 150 mg/kg. [9]
D. Isotretinoin has been effective in treating mild-to-moderate acne vulgaris in a double-blind, placebo-controlled study (n=127), for acne in a study of 156 patients, and for mild-to-moderate acne vulgaris in a double-blind study (n=268) [11]. Additionally, the American Academy of Dermatology recommends isotretinoin for the treatment of severe nodular acne, and states that it may be appropriate for the treatment of moderate acne that is treatment-resistant or for the management of acne that is producing physical scarring and/or psychosocial distress [9].

5 . References

1. Absorica/Absorica LD Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. June 2023.
2. Haider A, Shaw JC. Treatment of acne vulgaris. JAMA. 2004;292(6):726-735.
3. Gollnick H, Cunliffe W, Berson D, et al. Management of Acne: A report from a global alliance to improve outcomes in acne. J Am Acad Dermatol. 2003;49(suppl 1):S1-38.
4. Goldsmith LA, Bolognia JL, Callen JP, et al. American Academy of Dermatology concensus conference on the safe and optimal use of isotretinoin: Summary and recommendations. J Am Acad Dermatol. 2004;50:900-6.
5. Leyden JJ. A review of the use of combination therapies for the treatment of acne vulgaris. J Am Acad Dermatol. 2003;49(3):S200-S210.
6. American Academy of Dermatology. Clinical Guidelines of Care for Acne Vulgaris Management. Available at: http://www.aad.org/education/clinical-guidelines. Accessed January 2, 2024.
7. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically. Available by subscription at: http://www.thomsonhc.com/. Accessed January 2, 2024.

Prior Authorization Guideline

Guideline ID	GL-228445
Guideline Name	Iwilfin (eflornithine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Iwilfin (eflornithine)
High-risk neuroblastoma (HRNB) Indicated to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.

2 . Criteria

Product Name:Iwilfin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IWILFIN	EFLORNITHINE HCL TAB 192 MG	21757220300320	Brand

Approval Criteria

1 - Diagnosis of high-risk neuroblastoma (HRNB)

AND

2 - Patient has shown at least a partial response to prior multiagent, multimodality therapy as evidenced by ALL of the following [2]:

- 30% or more decrease in longest diameter of primary site tumor
- No new lesions
- MIBG (or 18F-FDG PET) stable or improved
- At least a 50% reduction in absolute MIBG bone score or a 50% or greater reduction in number of 18F-FDG PET-avid bone lesions

AND

3 - Prior therapy included anti-GD2 immunotherapy (e.g., Unituxin (dinutuximab))

AND

4 - Treatment duration of Iwilfin has not exceeded a total of 24 months during the patient's lifetime

Product Name:Iwilfin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IWILFIN	EFLORNITHINE HCL TAB 192 MG	21757220300320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Treatment duration of Iwilfin has not exceeded a total of 24 months during the patient's lifetime

3 . References

1. Iwilfin Prescribing Information. US WorldMeds, Louisville, KY, December 2023.
2. PDQ® Pediatric Treatment Editorial Board. PDQ Neuroblastoma Treatment. Bethesda, MD: National Cancer Institute. Updated <02/13/2024>. Available at: https://www.cancer.gov/types/neuroblastoma/hp/neuroblastoma-treatment-pdq. Accessed <2/28/2024>. [PMID: 26389190]
3. Consult with pediatric hematology/oncology consultant. 26 Feb 2024

Izervay (avacincaptad pegol)

Prior Authorization Guideline

Guideline ID	GL-233205
Guideline Name	Izervay (avacincaptad pegol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/18/2023
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Izervay (avacincaptad pegol)
Geographic Atrophy (GA) Indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

2 . Criteria

Product Name:Izervay	
Approval Length	6 months [A, 1]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IZERVAY	AVACINCAPTAD PEGOL INTRAVITREAL SOLN 2 MG/0.1ML (20 MG/ML)	86456020102020	Brand

Approval Criteria

1 - Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration

AND

2 - Disease is confirmed by one of the following:

- Fundus photography (e.g. fundus autofluorescence [FAF])
- Optical coherence tomography (OCT)
- Fluorescein angiography

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Izervay	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IZERVAY	AVACINCAPTAD PEGOL INTRAVITREAL SOLN 2 MG/0.1ML (20 MG/ML)	86456020102020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in growth rate of GA lesion)

AND

2 - Patient has not exceeded a total of 12 months treatment per eye [B, 1]

3 . Endnotes

A. In GATHER1 and GATHER2, the mean rate of GA growth (slope) from baseline to Month 12, measured by Fundus Autofluorescence (FAF) was evaluated at 3 time points: baseline, Month 6, and Month 12. [1]
B. The recommended dose for Izervay is 2 mg (0.1 mL of 20 mg/mL solution) administered by intravitreal injection to each affected eye once monthly (approximately 28 ± 7 days) for up to 12 months. [1]

4 . References

1. Izervay Precribing Information. Iveric Bio, Inc. Parsippany, NJ. February 2024.
2. FDA Product Review. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217225Orig1s000TOC.cfm. Accessed September 11, 2023.
3. Lexicomp. Izervay. Available at: https://www.uptodate.com/contents/avacincaptad-pegol-drug-information?search=geotrophic%20atropgy%20secondary%20to%20amd&source=search_result&selectedTitle=5~150&usage_type=default&display_rank=5. Accessed September 11, 2023.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228897
Guideline Name	Jakafi (ruxolitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Jakafi (ruxolitinib)
Myelofibrosis Indicated for treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults. **Polycythemia Vera** Indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. **Acute Graft Versus Host Disease** Indicated for treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older. **Chronic Graft Versus Host Disease** Indicated for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

2 . Criteria

Product Name:Jakafi	
Diagnosis	Myelofibrosis
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - One of the following diagnoses:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

Product Name:Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	8 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - Diagnosis of polycythemia vera [1]

AND

2 - Trial and failure, contraindication, or intolerance to hydroxyurea [1]

Product Name:Jakafi	
Diagnosis	Myelofibrosis, Polycythemia Vera
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., spleen volume reduction, symptom improvement, hematocrit control)

Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a 2-month authorization should be issued one time for Jakafi gradual therapy discontinuation.

Product Name:Jakafi	
Diagnosis	Acute Graft Versus Host Disease
Approval Length	6 Month(s) [C]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - Diagnosis of acute graft-versus-host disease

AND

2 - Disease is steroid-refractory

AND

3 - Patient is 12 years of age or older

Product Name:Jakafi	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Patient is 12 years of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)

Product Name:Jakafi	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. Jakafi should be discontinued after 6 months if there is no spleen size reduction or symptom improvement since initiation of therapy. [1]
B. The initial authorization duration of 8 months is based on clinical trials (primary endpoint of hematocrit control and spleen volume reduction was evaluated at 32 weeks). [1]
C. Authorization duration of 6 months is based median time from response to death or need for new therapy for acute GVHD in clinical trials (173 days). Additionally, tapering of Jakafi may be considered after 6 months of treatment in patients with response who have discontinued therapeutic doses of corticosteroids. [1]

4 . References

1. Jakafi Prescribing Information. Incyte Corp. Wilmington, DE. January 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228448
Guideline Name	Jaypirca (pirtobrutinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Jaypirca (pirtobrutinib)
Mantle Cell Lymphoma (MCL) Indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton Tyrosine Kinase (BTK) inhibitor. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)** Indicated for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.

2 . Criteria

Product Name:Jaypirca	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAYPIRCA	PIRTOBRUTINIB TAB 50 MG	21532165000320	Brand
JAYPIRCA	PIRTOBRUTINIB TAB 100 MG	21532165000330	Brand

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has received at least two prior therapies for MCL, one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Calquence (acalabrutinib), Brukinsa (zanubrutinib)] [1, 2]

Product Name:Jaypirca	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

JAYPIRCA	PIRTOBRUTINIB TAB 50 MG	21532165000320	Brand
JAYPIRCA	PIRTOBRUTINIB TAB 100 MG	21532165000330	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Chronic Lymphocytic Leukemia (CLL)
- Small Lymphocytic Lymphoma (SLL)

AND

2 - Patient has received treatment for CLL/ SLL with both of the following therapies:

- BTK inhibitor therapy [e.g., Calquence (acalabrutinib), Brukinsa (zanubrutinib)]
- B-cell lymphoma 2 (BCL-2) inhibitor therapy [e.g., Venclexta (venetoclax)]

Product Name:Jaypirca	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAYPIRCA	PIRTOBRUTINIB TAB 50 MG	21532165000320	Brand
JAYPIRCA	PIRTOBRUTINIB TAB 100 MG	21532165000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Jaypirca Prescribing Information. Lilly USA, LLC. Indianapolis, IN. December 2023.
2. Clinical Consult with an oncologist March 9, 2023.

Prior Authorization Guideline

Guideline ID	GL-233207
Guideline Name	Jesduvroq (daprodustat) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/16/2023
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Jesduvroq (daprodustat)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months.

2 . Criteria

Product Name:Jesduvroq	
Approval Length	6 months [D, 1]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JESDUVROQ	DAPRODUSTAT TAB 1 MG	82402520000310	Brand
JESDUVROQ	DAPRODUSTAT TAB 2 MG	82402520000315	Brand
JESDUVROQ	DAPRODUSTAT TAB 4 MG	82402520000320	Brand
JESDUVROQ	DAPRODUSTAT TAB 6 MG	82402520000325	Brand
JESDUVROQ	DAPRODUSTAT TAB 8 MG	82402520000330	Brand

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Patient has been on dialysis for at least 4 months

AND

3 - Adequate iron stores confirmed by both of the following: [A-B, 1, 4]

- Patient's ferritin level is greater than 100mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Hemoglobin level less than 11 g/dL [E-G, 1,3,9]

AND

5 - Trial and failure, contraindication or intolerance to one of the following:

- Retacrit
- Procrit

- Aranesp

AND

6 - Prescribed by or in consultation with one of the following:

- hematologist
- nephrologist

AND

7 - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

Product Name:Jesduvroq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JESDUVROQ	DAPRODUSTAT TAB 1 MG	82402520000310	Brand
JESDUVROQ	DAPRODUSTAT TAB 2 MG	82402520000315	Brand
JESDUVROQ	DAPRODUSTAT TAB 4 MG	82402520000320	Brand
JESDUVROQ	DAPRODUSTAT TAB 6 MG	82402520000325	Brand
JESDUVROQ	DAPRODUSTAT TAB 8 MG	82402520000330	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increase in hemoglobin)

AND

2 - Hemoglobin level does not exceed 12g/dL [H, 1]

AND

3 - Adequate iron stores confirmed by both of the following:

- Patient's ferritin level is greater than 100mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Trial and failure, contraindication or intolerance to one of the following:

- Retacrit
- Procrit
- Aranesp

AND

5 - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

Product Name:Jesduvroq	
Approval Length	6 months [D, 1]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
JESDUVROQ	DAPRODUSTAT TAB 1 MG	82402520000310	Brand
JESDUVROQ	DAPRODUSTAT TAB 2 MG	82402520000315	Brand
JESDUVROQ	DAPRODUSTAT TAB 4 MG	82402520000320	Brand
JESDUVROQ	DAPRODUSTAT TAB 6 MG	82402520000325	Brand
JESDUVROQ	DAPRODUSTAT TAB 8 MG	82402520000330	Brand

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has been on dialysis for at least 4 months

AND

3 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [A-B, 1, 4]

- Patient's ferritin level is greater than 100mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Submission of medical records (e.g., chart notes) confirming hemoglobin level less than 11 g/dL [E-G, 1,3,9]

AND

5 - One of the following:

5.1 Submission of medical records (e.g., chart notes) or paid claims confirming a minimum 12 -week trial and failure to one of the following: [I, 10-12]

- Retacrit
- Procrit
- Aranesp

OR

5.2 Submission of medical records (e.g., chart notes) confirming contraindication or intolerance to ALL of the following:

- Retacrit
- Procrit

- Aranesp

AND

6 - Prescribed by or in consultation with one of the following:

- hematologist
- nephrologist

AND

7 - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

Product Name:Jesduvroq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
JESDUVROQ	DAPRODUSTAT TAB 1 MG	82402520000310	Brand
JESDUVROQ	DAPRODUSTAT TAB 2 MG	82402520000315	Brand
JESDUVROQ	DAPRODUSTAT TAB 4 MG	82402520000320	Brand
JESDUVROQ	DAPRODUSTAT TAB 6 MG	82402520000325	Brand
JESDUVROQ	DAPRODUSTAT TAB 8 MG	82402520000330	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increase in hemoglobin)

AND

2 - Submission of medical records (e.g., chart notes) confirming hemoglobin level does not exceed 12g/dL [H, 1]

AND

3 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following:

- Patient's ferritin level is greater than 100mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - One of the following:

4.1 Submission of medical records (e.g., chart notes) or paid claims confirming a minimum 12 -week trial and failure to one of the following: [I, 10-12]

- Retacrit
- Procrit
- Aranesp

OR

4.2 Submission of medical records (e.g., chart notes) confirming contraindication or intolerance to ALL of the following:

- Retacrit
- Procrit
- Aranesp

AND

5 - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

3 . Endnotes

A. Evaluate the iron status in all patients before and during treatment with Jesduvroq. Administer supplemental iron therapy when serum ferritin is less than 100 ng/ml or when serum transferrin saturation is less than 20%. [1]
B. Clinical Trials Exclusion criteria: Ferritin less than or equal to 100mcg/L and transferrin saturation (TSAT) less than or equal to 20% at screening [4]
C. In this randomized, open-label, phase 3 trial, we assigned patients with CKD who were undergoing dialysis and who had a hemoglobin level of 8.0 to 11.5 g per deciliter to receive an oral HIF-PHI (daprodustat) or an injectable ESA (epoetin alfa if they were receiving hemodialysis or darbepoetin alfa if they were receiving peritoneal dialysis). [2]
D. The efficacy and safety of Jesduvroq were evaluated as co-primary endpoints: the mean change in hemoglobin from baseline to the Evaluation Period (Weeks 28 to 52) [1]
E. Ascend-D trial the target hemoglobin range was 10-11g/dL [3]
F. Do not target a hemoglobin higher than 11 g/dL [1]
G. Using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular events and has not been shown to provide additional patient benefit [9]
H. If hemoglobin exceeds 12 g/dL, interrupt treatment with Jesduvroq [1]
I. Do not increase the dose more frequently than once every 4 weeks. For patients who do not respond adequately, if the hemoglobin has not increased by more than 1 g/dL after 4 weeks of therapy, increase the dose by 25%. For patients who do not respond adequately over a 12-week escalation period, increasing the Retacrit dose further is unlikely to improve response and may increase risks. Use the lowest dose that will maintain a hemoglobin level sufficient to reduce the need for RBC transfusions. Evaluate other causes of anemia. Discontinue Retacrit if responsiveness does not improve. [10-12]

4 . References

1. Jesduvroq Prescribing Information. GlaxoSmithKline. Durham, NC. February 2023.
2. Singh, A., Carroll, K., et al. Daprodustat for the Treatment of Anemia in Patients Undergoing Dialysis. Available at: https://www.nejm.org/doi/10.1056/NEJMoa2113379?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed. Accessed October 16, 2023.
3. Singh, A., Blackorby, A., et al. Study design and baseline characteristics of patients on dialysis in the ASCEND-D trial. Available at: https://academic.oup.com/ndt/article/37/5/960/6179323?login=true. Accessed October 16, 2023.
4. ClinicalTrials.gov. Anemia Studies in Chronic Kidney Disease: Erythropoiesis Via a Novel Prolyl Hydroxylase Inhibitor Daprodustat-Dialysis (ASCEND-D). Available at: https://www.clinicaltrials.gov/study/NCT02879305?term=NCT02879305&rank=1. Accessed October 16, 2023.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279-335. Available at: https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-Anemia-Guideline-English.pdf. Accessed October 16, 2023.

6. Kliger, A., Foley, R., et al. KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. Available at: https://www.ajkd.org/article/S0272-6386(13)00978-5/fulltext. Accessed October 16, 2023.
7. UptoDate. Treatment of anemia in patients on dialysis. Available at: https://www.uptodate.com/contents/treatment-of-anemia-in-patients-on-dialysis?search=anemia%20in%20chronic%20kidney%20disease&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4#. Accessed Ocober 16, 2023.
8. UptoDate. Diagnosis of iron deficiency in chronic kidney disease. Available at: https://www.uptodate.com/contents/diagnosis-of-iron-deficiency-in-chronic-kidney-disease?search=anemia%20in%20chronic%20kidney%20disease&topicRef=1953&source=see_link. Accessed October 16, 2023.
9. FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-modified-dosing-recommendations-improve-safe-use-erythropoiesis. Accessed November 8, 2023.
10. Retacrit Prescribing Information. Hospira, Inc. Lake Forest, IL. April 2023.
11. Procrit Prescribing Information. Amgen Inc. Thousand Oaks, CA. July 2018.
12. Aranesp Prescribing Information. Amgen Inc. Thousand Oaks, CA. January 2019.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228449
Guideline Name	Jevtana (cabazitaxel)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Jevtana (cabazitaxel)
Prostate Cancer Indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

2 . Criteria

Product Name:Jevtana	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JEVTANA	CABAZITAXEL INJ 60 MG/1.5ML (FOR IV INFUSION)	21500003002020	Brand

Approval Criteria

1 - All of the following:

1.1 Diagnosis of metastatic castration-resistant prostate cancer

AND

1.2 Used in combination with prednisone

AND

1.3 Patient has been previously treated with a docetaxel-containing regimen

Product Name:Jevtana	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JEVTANA	CABAZITAXEL INJ 60 MG/1.5ML (FOR IV INFUSION)	21500003002020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease

3 . References

1. Jevtana Prescribing Information. Sanofi-Aventis U.S. LLC, Bridgewater, NJ. July 2023.

Prior Authorization Guideline

Guideline ID	GL-233268
Guideline Name	Juxtapid (lomitapide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Juxtapid (lomitapide)
Homozygous familial hypercholesterolemia (HoFH) Indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). Limitations of use: (1) The safety and effectiveness of Juxtapid have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH). (2) The effect of Juxtapid on cardiovascular morbidity and mortality has not been determined.

2 . Criteria

Product Name:Juxtapid	
Approval Length	6 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JUXTAPID	LOMITAPIDE MESYLATE CAP 5 MG (BASE EQUIV)	39480050200120	Brand
JUXTAPID	LOMITAPIDE MESYLATE CAP 10 MG (BASE EQUIV)	39480050200130	Brand
JUXTAPID	LOMITAPIDE MESYLATE CAP 20 MG (BASE EQUIV)	39480050200140	Brand
JUXTAPID	LOMITAPIDE MESYLATE CAP 30 MG (BASE EQUIV)	39480050200150	Brand

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by one of the following: [1-3]

1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

OR

1.2 Both of the following:

1.2.1 Untreated LDL-C greater than 400 mg/dL

AND

1.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - One of the following:

2.1 Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe) [A]

OR

2.2 Patient has an inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Trial and failure, contraindication, or intolerance to Repatha therapy

AND

4 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Hepatologist

AND

5 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

Product Name:Juxtapid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JUXTAPID	LOMITAPIDE MESYLATE CAP 5 MG (BASE EQUIV)	39480050200120	Brand
JUXTAPID	LOMITAPIDE MESYLATE CAP 10 MG (BASE EQUIV)	39480050200130	Brand
JUXTAPID	LOMITAPIDE MESYLATE CAP 20 MG (BASE EQUIV)	39480050200140	Brand
JUXTAPID	LOMITAPIDE MESYLATE CAP 30 MG (BASE EQUIV)	39480050200150	Brand

Approval Criteria

1 - One of the following:

1.1 Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe)

OR

1.2 Patient has an inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

2 - Reduction in LDL-C from baseline while on therapy

AND

3 - Trial and failure, contraindication, or intolerance to Repatha therapy

AND

4 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Hepatologist

AND

5 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

3 . Endnotes

A. IMPROVE-IT was a prospective RCT evaluating the addition of ezetimibe to simvastatin 40 mg in a high-risk patient population for secondary prevention over 7 years. The addition of ezetimibe significantly reduced ASCVD events, albeit very modestly (HR 0.936; 95% CI 0.887, 0.988; p = 0.016; number needed to treat [NNT] = 50). [5] The effect of lomitapide on cardiovascular morbidity and mortality has not been determined. [1]
B. Lipid specialists are physicians certified by the American Board of Clinical Lipidology (ABCL) or the Accreditation Council for Clinical Lipidology (ACCL). [6, 7] In the opinion of the ACC expert consensus writing committee, lomitapide is best administered under the care of a lipid specialist. [8]
C. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. [4]

4 . References

1. Juxtapid Prescribing Information. Aegerion Pharmaceuticals, Inc. Cambridge, MA. September 2020.
2. Raal FJ, Santos RD. Homozygous familial hypercholesterolemia: current perspectives on diagnosis and treatment. Atherosclerosis. 2012;223:262-8.
3. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014;35:2146-57.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.
5. Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. N Engl J Med. 2015;372:2387-97.
6. American Board of Clinical Lipidology website. www.lipidboard.org. Accessed September 3, 2020.
7. Accreditation Council for Clinical Lipidology website. www.lipidspecialist.org. Accessed September 3, 2020.
8. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholersterol lowering in the management of atherosclerotic cardiovascular disease risk. J Am Coll Cardiol. 2017;70:1785-1822.
9. Cuchel M, Raal FJ, Hegele RA, et al. 2023 Update on European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolaemia: new treatments and clinical guidance. Eur Heart J. 2023;44(25):2277-2291. doi:10.1093/eurheartj/ehad197

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228899
Guideline Name	Kalydeco (ivacaftor)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Kalydeco (ivacaftor)
Cystic fibrosis Indicated for the treatment of cystic fibrosis (CF) in patients age 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

2 . Criteria

Product Name:Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KALYDECO	IVACAFTOR TAB 150 MG	45302030000320	Brand
KALYDECO	IVACAFTOR PACKET 50 MG	45302030003020	Brand
KALYDECO	IVACAFTOR PACKET 75 MG	45302030003030	Brand
KALYDECO	IVACAFTOR PACKET 13.4 MG	45302030003005	Brand
KALYDECO	IVACAFTOR PACKET 25 MG	45302030003010	Brand
KALYDECO	IVACAFTOR PACKET 5.8 MG	45302030003002	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data* as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 1 month of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a CF care center
- Pulmonologist

Notes	*Please consult Background section for table of CFTR gene mutations responsive to Kalydeco.

Product Name:Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KALYDECO	IVACAFTOR TAB 150 MG	45302030000320	Brand
KALYDECO	IVACAFTOR PACKET 50 MG	45302030003020	Brand
KALYDECO	IVACAFTOR PACKET 75 MG	45302030003030	Brand
KALYDECO	IVACAFTOR PACKET 25 MG	45302030003010	Brand
KALYDECO	IVACAFTOR PACKET 13.4 MG	45302030003005	Brand
KALYDECO	IVACAFTOR PACKET 5.8 MG	45302030003002	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response (i.e., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}], decreased number of pulmonary exacerbations) to therapy [A]

3 . Background

Clinical Practice Guidelines

CFTR Gene Mutations that are Responsive to Kalydeco [1]

*Intent of table is to provide a quick reference; PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 1/24/24]

List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to KALYDE				
*711+3A→G **	*F311del*	*I148T*	*R75Q*	*S589N*
*2789+5G→A **	*F311L*	*I175V*	*R117C **	*S737F*
*3272-26A→G **	*F508C*	*I807M*	*R117G*	*S945L **

*3849+10kbC→T *	*F508C;S1251N †	*I1027T*	*R117H *	*S977F *
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W *	*R170H*	*S1251N *
*A455E *	*G178R *	*L320V*	*R347H *	*S1255P *
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q *	*T1053I*
D110H	*G551D *	*L1480P*	*R553Q*	*V232D*
D192G	*G551S *	*M152V*	*R668C*	*V562I*
*D579G *	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
*D1152H *	*G1069R*	*P67L *	*R1070Q*	*W1282R*
D1270N	*G1244E *	*Q237E*	*R1070W *	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D *	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N *	
*E831X *	*H1375P*	*R74W*	*S549R *	

** Clinical data exist for these mutations.*

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations these exist independent of the presence of mutations on the other allele.

4 . Endnotes

A. The primary efficacy endpoint in both Kalydeco pivotal trials was improvement in lung function as determined by the mean absolute change from baseline in percent predicted pre-dose FEV1 through 24 weeks of treatment. [2]

5 . References

1. Kalydeco Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. August 2023.
2. Ramsey BW, Davies J, McElvaney G, et al. A CFTR potentiator in patients with cystic fibrosis and the G551D mutation. N Engl J Med. 2011;365:1663-1672.

6 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228671
Guideline Name	Kanuma (sebelipase alfa)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Kanuma (sebelipase alfa)
Lysosomal Acid Lipase (LAL) deficiency Indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency.

2 . Criteria

Product Name:Kanuma	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KANUMA	SEBELIPASE ALFA IV SOLN 20 MG/10ML (2 MG/ML)	30906360002020	Brand

Approval Criteria

1 - Diagnosis of lysosomal acid lipase deficiency (LAL-D, Wolman Disease, Cholesteryl ester storage disease) [B]

AND

2 - Diagnosis was confirmed by one of the following: [A]

2.1 Enzymatic blood test (e.g., dried blood spot test) demonstrating a deficiency of LAL enzyme activity

OR

2.2 Genetic testing for mutations in the lipase A, lysosomal acid type (LIPA) gene

AND

3 - Prescribed by or in consultation with one of the following:

- A specialist experienced in the treatment of inborn errors of metabolism
- Gastroenterologist
- Lipidologist

Product Name:Kanuma	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

KANUMA	SEBELIPASE ALFA IV SOLN 20 MG/10ML (2 MG/ML)	30906360002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in LDL, triglycerides, AST or ALT, increase in HDL, reduction in liver fat content)

AND

2 - Prescribed by or in consultation with one of the following:

- A specialist experienced in the treatment of inborn errors of metabolism
- Gastroenterologist
- Lipidologist

3 . Endnotes

A. Due to similar clinical presentations, LAL-D is often misdiagnosed as familial defective apolipoprotein B (ApoB) deficiency, heterozygous familial hypercholesterolemia (HeFH), familial combined hyperlipidemia (FCH), or polygenic hypercholesterolaemia [3]. A diagnosis of LAL-D can be confirmed by identification of a LIPA mutation or a deficient LAL enzyme in peripheral blood leukocytes, fibroblasts, or dried blood spots. A biopsy and/or radiographic findings may help support a LAL-D diagnosis, however these are not considered diagnostic. [2,3]
B. LAL deficiency is sub-classified as Wolman disease in infants and cholesteryl ester storage disease (CESD) in children and adults. [4]

4 . References

1. Kanuma prescribing information, Alexion Pharmaceuticals. Cheshire, CT. November 2021.
2. Burton BK, Balwani M, Feillet F, et al. A Phase 3 Trial of Sebelipase Alfa in Lysosomal Acid Lipase Deficiency. N Engl J Med. 2015;373(11):1010-20.
3. Reiner, Guardamagna, Nair, et al. Lysosomal acid lipase deficiency - an under-recognized cause of dyslipidaemia and liver dysfunction. Atherosclerosis. 2014;235(1): 21-30.
4. Strebinger G, Müller E, Feldman A, Aigner E. Lysosomal acid lipase deficiency - early diagnosis is the key. Hepat Med. 2019 May 23;11:79-88.

Kerendia (finerenone)

Prior Authorization Guideline

Guideline ID	GL-228451
Guideline Name	Kerendia (finerenone)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Kerendia (finerenone)
Chronic Kidney Disease Associated with Type 2 Diabetes Indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).

2 . Criteria

Product Name:Kerendia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KERENDIA	FINERENONE TAB 10 MG	30354030000310	Brand
KERENDIA	FINERENONE TAB 20 MG	30354030000320	Brand

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

AND

2 - Urine albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g

AND

3 - Estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m2

AND

4 - Serum potassium level less than or equal to 5.0 mEq/L prior to initiating treatment

AND

5 - One of the following:

5.1 Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following [2]:

- Generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- Generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

AND

6 - One of the following:

6.1 Patient is on a stable dose and will continue therapy with a sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin])

OR

6.2 Patient has a contraindication or intolerance to an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin])

Product Name:Kerendia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KERENDIA	FINERENONE TAB 10 MG	30354030000310	Brand
KERENDIA	FINERENONE TAB 20 MG	30354030000320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB

OR

2.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

AND

3 - One of the following:

3.1 Patient continues to be on an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin])

OR

3.2 Patient has a contraindication or intolerance to an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin])

3 . References

1. Kerendia Prescribing Information. Bayer Healthcare Pharmaceuticals Inc. Whippany, NJ. September 2022.
2. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney Int. 2022;102(5S): S1-S127.

Prior Authorization Guideline

Guideline ID	GL-228611
Guideline Name	Kevzara (sarilumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Kevzara (sarilumab)
Rheumatoid Arthritis (RA) Indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs). **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients who weigh 63 kg or greater. **Polymyalgia Rheumatica (PMR)** Indicated for treatment of adult patients with polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

2 . Criteria

Product Name:Kevzara	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/1.14ML	6650006000E520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	6650006000E530	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/1.14ML	6650006000D520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/1.14ML	6650006000D530	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

4.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor. ** For review process only: Refer to the table in the Background sectio n for carrier-specific formulary adalimumab products

Product Name:Kevzara	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/1.14ML	6650006000E520	Brand

KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	6650006000E530	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/1.14ML	6650006000D520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/1.14ML	6650006000D530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Kevzara	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/1.14ML	6650006000E520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	6650006000E530	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/1.14ML	6650006000D520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/1.14ML	6650006000D530	Brand

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA)

AND

2 - Patient weighs at least 63 kg

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Enbrel (etanercept)
- One formulary adalimumab product
- Rinvoq/LQ (upadacitinib)
- Xeljanz (tofacitinib)

AND

5.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

5.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. ** For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products

Product Name:Kevzara	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/1.14ML	6650006000E520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	6650006000E530	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/1.14ML	6650006000D520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/1.14ML	6650006000D530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Kevzara	
Diagnosis	Polymyalgia Rheumatica (PMR)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/1.14ML	6650006000E520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	6650006000E530	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/1.14ML	6650006000D520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/1.14ML	6650006000D530	Brand

Approval Criteria

1 - Diagnosis of polymyalgia rheumatica (PMR)

AND

2 - One of the following:

2.1 Patient has had an inadequate response to corticosteroids (e.g., prednisone)

OR

2.2 Patient cannot tolerate tapering of corticosteroids (e.g., prednisone)

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name:Kevzara	
Diagnosis	Polymyalgia Rheumatica (PMR)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/1.14ML	6650006000E520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	6650006000E530	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/1.14ML	6650006000D520	Brand
KEVZARA	SARILUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/1.14ML	6650006000D530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Improvement in symptoms (e.g., pain, stiffness) or lab values (e.g., C-reactive protein) from baseline
- Reduced need for corticosteroids (e.g., prednisone)

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products Adalimumab-adaz Hyrimoz Hadlima Adalimumab-fkjp

4 . References

1. Kevzara prescribing information. sanofi-aventis U.S. LLC. Bridgewater, NJ. February 2023.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
5. Dejaco C, Singh YP, Perel P, et al. 2015 recommendations for the management of polymyalgia rheumatica: a European League Against Rheumatism/American College of Rheumatology collaborative initiative. 2015;74(10):1799-807.

5 . Revision History

Date	Notes
11/8/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-233389
Guideline Name	Khapzory (levoleucovorin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	1/15/2020
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Khapzory (levoleucovorin)
Rescue After High-Dose Methotrexate Therapy Indicated for rescue after high-dose methotrexate therapy in adult and pediatric patients with osteosarcoma. Limitations of use: Khapzory is not indicated for the treatment of pernicious anemia and megaloblastic anemia secondary to lack of vitamin B12 because of the risk of progression of neurologic manifestations despite hematologic remission. **Overdosage of Folic Acid Antagonists or Impaired Methotrexate Elimination** Indicated for diminishing the toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination adult and pediatric patients. Limitations of use: Khapzory is not indicated for the treatment of pernicious anemia and megaloblastic anemia secondary to lack of vitamin B12 because of the risk of progression of neurologic manifestations despite hematologic remission. **Metastatic Colorectal Cancer** Indicated for the treatment of adults with metastatic colorectal cancer in combination with fluorouracil. Limitations of use: Khapzory is not indicated for the

treatment of pernicious anemia and megaloblastic anemia secondary to lack of vitamin B12 because of the risk of progression of neurologic manifestations despite hematologic remission.

2 . Criteria

Product Name:Khapzory	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
KHAPZORY	LEVOLEUCOVORIN FOR IV SOLN 175 MG	21755050002120	Brand
KHAPZORY	LEVOLEUCOVORIN FOR IV SOLN 300 MG	21755050002130	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30-day supply) or intolerance to generic levoleucovorin

OR

2 - For continuation of prior therapy

3 . References

1. Khapzory. Prescribing information. Acrotech Biopharma, LLC. East Windsor, NJ; December 2024.

4 . Revision History

Date	Notes
3/14/2025	Quartz guideline copied to mirrow Optumrx

Prior Authorization Guideline

Guideline ID	GL-228454
Guideline Name	Kimmtrak (tebentafusp-tebn)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Kimmtrak (tebentafusp-tebn) injection, for intravenous use
Uveal Melanoma Indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

2 . Criteria

Product Name:Kimmtrak	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KIMMTRAK	TEBENTAFUSP-TEBN IV SOLN 100 MCG/0.5ML	21352080602020	Brand

Approval Criteria

1 - Diagnosis of uveal melanoma

AND

2 - Disease is unresectable or metastatic

AND

3 - Patient is HLA-A*02:01 genotype positive as determined by a high-resolution genotyping test [2]

Product Name:Kimmtrak	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KIMMTRAK	TEBENTAFUSP-TEBN IV SOLN 100 MCG/0.5ML	21352080602020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Kimmtrak Prescribing Information. Immunocore Commercial LLC. Conshohocken, PA. January 2022.

2. Nunes E, Heslop H, Fernandez-Vina M, et al. Definitions of histocompatibility typing terms. Blood. 2011;118(23):e180-e183.

Prior Authorization Guideline

Guideline ID	GL-228614
Guideline Name	Kineret (anakinra)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Kineret (anakinra)
Rheumatoid Arthritis (RA) Indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis (RA), in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs). Kineret can be used alone or in combination with DMARDs other than tumor necrosis factor (TNF) blocking agents. **Cryopyrin-Associated Periodic Syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]** Indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID). **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)** Indicated for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA). **Off Label Uses: Systemic Juvenile Idiopathic Arthritis (SJIA)** Has been used for the treatment of systemic juvenile idiopathic arthritis. [7]

2 . Criteria

Product Name:Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KINERET	ANAKINRA SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	6626001000E520	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - One of the following:

4.1 All of the following:

4.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

4.2 For continuation of prior Kineret therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. ** For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products

Product Name:Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KINERET	ANAKINRA SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	6626001000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KINERET	ANAKINRA SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	6626001000E520	Brand

Approval Criteria

1 - Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

AND

2 - Diagnosis of NOMID has been confirmed by one of the following: [5-6, B]

2.1 NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3-gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation

OR

2.2 Both of the following:

2.2.1 Two of the following clinical symptoms:

- Urticaria-like rash
- Cold/stress triggered episodes
- Sensorineural hearing loss
- Musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia)
- Chronic aseptic meningitis
- Skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing)

AND

2.2.2 Elevated acute phase reactants (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA])

AND

3 - Prescribed by or in consultation with one of the following

- Allergist/Immunologist
- Rheumatologist
- Pediatrician

Product Name:Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KINERET	ANAKINRA SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	6626001000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Kineret	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KINERET	ANAKINRA SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	6626001000E520	Brand

Approval Criteria

1 - Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)

Product Name:Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA) (Off-Label)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KINERET	ANAKINRA SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	6626001000E520	Brand

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis [7]

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [7]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone)

Product Name:Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA) (Off-Label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KINERET	ANAKINRA SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	6626001000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [7]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

3 . Background

Benefit/Coverage/Program Information

Formulary Adalimumab Products

Adalimumab-adaz

Hyrimoz

Hadlima

Adalimumab-fkjp

4 . Endnotes

A. Three clinically overlapping, interleukin-1-associated, autoinflammatory disorders are known collectively as the cryopyrin-associated periodic syndromes (CAPS) or cryopyrinopathies: familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), and neonatal onset multisystem inflammatory disorder (NOMID, also known as chronic infantile neurological cutaneous and articular [CINCA] syndrome). [4]
B. In addition to clinical symptoms, a diagnosis should be made using a combination of procedures including laboratory assessments, skin biopsy, and genetic testing. [5] Diagnostic criteria developed by a multidisciplinary team of international experts in the care of children and adults with CAPS found that the best diagnosis criteria model included: raised inflammatory markers (CRP/SAA) plus two or more of six CAPS-typical signs/symptoms including (1) urticaria-like rash, (2) cold-triggered episodes, (3) sensorineural hearing loss, (4) musculoskeletal symptoms (arthralgia/arthritis/myalgia), (5) chronic aseptic meningitis, and (6) skeletal abnormalities (epiphyseal overgrowth/frontal bossing). This proposed model had a sensitivity of 81% and a specificity of 94%. It performed equally well for all CAPS subtypes and in subgroups with and without evidence of NLRP3 mutation ($p < 0.001$). [4, 6]

5 . References

1. Kineret Prescribing Information. Swedish Orphan Biovitrum. Stockholm, Sweden. December 2020.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Rheumatol. 2021;73(7):1108-23.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
4. Nigrovic PA. Cryopyrin-associated periodic syndromes and related disorders. UpToDate. Updated February 6, 2023. http:www.uptodate.com. Accessed January 28, 2024.
5. Yu JR and Leslie KS. Cryopyrin-associated periodic syndrome: an update on diagnosis and treatment response. Curr Allergy Asthma Rep. 2011;11(1):12-20
6. Kuemmerle-Deschner JB, Ozen S, Tyrrell PN, et al. Diagnostic criteria for cryopyrin-associated periodic syndrome (CAPS). Ann Rheum Dis. 2017 Jun;76(6):942-947.
7. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis,

temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.

6 . Revision History

Date	Notes
11/8/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-233238
Guideline Name	Kisqali (ribociclib), Kisqali Femara Co-Pack (letrozole and ribociclib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	4/26/2017
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Kisqali (ribociclib)
Advanced or Metastatic Breast cancer Indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic cancer in combination with one of the following: (1) an aromatase inhibitor as initial endocrine-based therapy, (2) fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy. **Early Breast Cancer** Indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR) – positive, human epiderma growth factor receptor 2 (HER2) – negative stage II and III early breast cancer at high risk of recurrence.
Drug Name: Kisqali Femara Co-Pack (letrozole and ribociclib)
Advanced or Metastatic Breast cancer Indicated as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

Early Breast Cancer Indicated for the adjuvant treatment of adults with hormone receptor (HR) – positive, human epidermal growth factor receptor 2 (HER2) – negative stage II or III early breast cancer at high risk of recurrence.

2 . Criteria

Product Name:Kisqali, Kisqali Femara Co-Pack	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 200 MG DAILY DOSE	2153107050B720	Brand
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 400 MG DAILY DOSE (200 MG TAB)	2153107050B740	Brand
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 600 MG DAILY DOSE (200 MG TAB)	2153107050B760	Brand
KISQALI FEMARA 200 DOSE	RIBOCICLIB 200 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B730	Brand
KISQALI FEMARA 400 DOSE	RIBOCICLIB 400 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B740	Brand
KISQALI FEMARA 600 DOSE	RIBOCICLIB 600 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B760	Brand

Approval Criteria

1 - Diagnosis of breast cancer

Product Name:Kisqali, Kisqali Femara Co-Pack	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 200 MG DAILY DOSE	2153107050B720	Brand
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 400 MG DAILY DOSE (200 MG TAB)	2153107050B740	Brand
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 600 MG DAILY DOSE (200 MG TAB)	2153107050B760	Brand
KISQALI FEMARA 200 DOSE	RIBOCICLIB 200 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B730	Brand
KISQALI FEMARA 400 DOSE	RIBOCICLIB 400 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B740	Brand
KISQALI FEMARA 600 DOSE	RIBOCICLIB 600 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B760	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Kisqali prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. September 2024..
2. Kisqali Femara Co-Pack prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. September 2024.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-229069
Guideline Name	Kisqali (ribociclib), Kisqali Femara Co-Pack (letrozole and ribociclib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Kisqali (ribociclib)
Breast cancer Indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic cancer in combination with one of the following: (1) an aromatase inhibitor as initial endocrine-based therapy, (2) fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.
Drug Name: Kisqali Femara Co-Pack (letrozole and ribociclib)
Breast cancer Indicated as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

2 . Criteria

Product Name:Kisqali, Kisqali Femara Co-Pack	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 200 MG DAILY DOSE	2153107050B720	Brand
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 400 MG DAILY DOSE (200 MG TAB)	2153107050B740	Brand
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 600 MG DAILY DOSE (200 MG TAB)	2153107050B760	Brand
KISQALI FEMARA 200 DOSE	RIBOCICLIB 200 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B730	Brand
KISQALI FEMARA 400 DOSE	RIBOCICLIB 400 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B740	Brand
KISQALI FEMARA 600 DOSE	RIBOCICLIB 600 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B760	Brand

Approval Criteria

1 - Diagnosis of breast cancer

Product Name:Kisqali, Kisqali Femara Co-Pack	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 200 MG DAILY DOSE	2153107050B720	Brand
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 400 MG DAILY DOSE (200 MG TAB)	2153107050B740	Brand
KISQALI	RIBOCICLIB SUCCINATE TAB PACK 600 MG DAILY DOSE (200 MG TAB)	2153107050B760	Brand

KISQALI FEMARA 200 DOSE	RIBOCICLIB 200 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B730	Brand
KISQALI FEMARA 400 DOSE	RIBOCICLIB 400 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B740	Brand
KISQALI FEMARA 600 DOSE	RIBOCICLIB 600 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK	2199000260B760	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Kisqali prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2024.
2. Kisqali Femara Co-Pack prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2023.

Prior Authorization Guideline

Guideline ID	GL-228674
Guideline Name	Korlym (mifepristone)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Korlym (mifepristone)
Hyperglycemia in Patients with Endogenous Cushing's Syndrome and Type 2 Diabetes Mellitus Indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Limitations of use: Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.

2 . Criteria

Product Name:Brand Korlym, Generic mifepristone 300mg	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KORLYM	MIFEPRISTONE TAB 300 MG	27304050000330	Brand
MIFEPRISTONE	MIFEPRISTONE TAB 300 MG	27304050000330	Generic

Approval Criteria

1 - Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids) [A]

AND

2 - One of the following:

- Diagnosis of type 2 diabetes mellitus
- Diagnosis of glucose intolerance

AND

3 - Patient has hyperglycemia that is secondary to hypercortisolism

AND

4 - One of the following: [1,2]

- Patient has failed surgery
- Patient is not a candidate for surgery

AND

5 - Trial or intolerance to generic mifepristone 300 mg (applies to Brand Korlym only)

AND

6 - Prescribed by or in consultation with an endocrinologist

AND

7 - Patient is not pregnant [1]

Product Name:Brand Korlym, Generic mifepristone 300mg	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KORLYM	MIFEPRISTONE TAB 300 MG	27304050000330	Brand
MIFEPRISTONE	MIFEPRISTONE TAB 300 MG	27304050000330	Generic

Approval Criteria

1 - Documentation of one of the following:

- Patient has improved glucose tolerance while on therapy
- Patient has stable glucose tolerance while on therapy

AND

2 - Trial or intolerance to generic mifepristone 300 mg (applies to Brand Korlym only)

3 . Endnotes

A. Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome. [1]

4 . References

1. Korlym prescribing information. Corcept Therapeutics Inc. Menlo Park, CA. November 2019.
2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(8):2807-2831.
3. Mifepristone prescribing information. Actavis Pharma, Inc. May 2024.

Prior Authorization Guideline

Guideline ID	GL-228676
Guideline Name	Korsuva (difelikefalin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Korsuva (difelikefalin) injection
Chronic kidney disease (CKD) Indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD). Limitations of use: Korsuva has not been studied in patients on peritoneal dialysis and is not recommended for use in this population.

2 . Criteria

Product Name:Korsuva	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KORSUVA	DIFELIKEFALIN ACETATE 65 MCG/1.3ML (50 MCG/ML)	99690020102020	Brand

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Patient is currently undergoing hemodialysis (HD) at an optimal dialysis dose (e.g., Kt/V greater than or equal to 1.2) [A, B, 4]

AND

3 - Patient is experiencing moderate to severe pruritus associated with CKD (CKD-aP)

AND

4 - Exclusion of other causes of pruritus (e. g., eczema, infections, drug-induced skin dryness) [C, 3]

AND

5 - Trial and failure, contraindication, or intolerance to ONE topical anti-pruritic treatment: [2,3]

- emollient cream
- analgesics (e.g., pramoxine lotion, capsaicin)
- corticosteroids (e.g., hydrocortisone, triamcinolone)

AND

6 - Trial and failure, contraindication, or intolerance to ONE oral treatment: [2,3]

- antihistamine (e.g., diphenhydramine, hydroxyzine, loratadine)

- gabapentin
- pregabalin

AND

7 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Dermatologist

Product Name:Korsuva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KORSUVA	DIFELIKEFALIN ACETATE 65 MCG/1.3ML (50 MCG/ML)	99690020102020	Brand

Approval Criteria

1 - Patient is currently undergoing hemodialysis [A]

AND

2 - Patient demonstrates positive clinical response to therapy (e.g., improved quality of life, improved worst itching intensity numerical rating score from baseline)

3 . Endnotes

A. Korsuva is administered by intravenous bolus injection into the venous line of the dialysis circuit at the end of each HD treatment. [1]
B. On average, a Kt/V of 1.2 is roughly equivalent to a URR of about 63 percent. Thus, another standard of adequate dialysis is a minimum Kt/V of 1.2. The Kidney Disease

Outcomes Quality Initiative (KDOQI) group has adopted the Kt/V of 1.2 as the standard for dialysis adequacy. [4]

C. Pruritus associated with Chronic Kidney Disease (CKD-aP), previously known as uremic pruritus, may vary from a localized itch, commonly in the back, face, and arms, to a generalized itch involving the entire body. Primary skin lesions may present with similar symptoms, and any suspicion of an underlying primary lesion should be first evaluated by dermatology. [3]

4 . References

1. Korsuva Prescribing Information. Cara Therapeutics, Inc. Stamford, CT. August 2021.
2. Davison SN, Levin A, Moss AH, et al. Executive summary of the KDIGO Controversies Conference on Supportive Care in Chronic Kidney Disease: developing a roadmap to improving quality care. Kidney International. 2015;88(3):447-459.
3. Ragazzo J, Cesta A, Jassal SV, Chiang N, Battistella M. Development and Validation of a Uremic Pruritus Treatment Algorithm and Patient Information Toolkit in Patients With Chronic Kidney Disease and End Stage Kidney Disease. Journal of Pain and Symptom Management. 2020;59(2):279-292.e5.
4. Hemodialysis: Dose & Adequacy | NIDDK. National Institute of Diabetes and Digestive and Kidney Diseases. Accessed April 4, 2022.

Prior Authorization Guideline

Guideline ID	GL-228898
Guideline Name	Koselugo (selumetinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Koselugo (selumetinib)
Neurofibromatosis Type 1 Indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN)

2 . Criteria

Product Name:Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KOSELUGO	SELUMETINIB SULFATE CAP 10 MG	21533565500110	Brand
KOSELUGO	SELUMETINIB SULFATE CAP 25 MG	21533565500125	Brand

Approval Criteria

1 - Diagnosis of neurofibromatosis type 1

AND

2 - Patient has plexiform neurofibromas that are both of the following:

- Inoperable [B]
- Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment)

AND

3 - One of the following:

3.1 Patient is less than 18 years of age

OR

3.2 Both of the following:

- Patient is 18 years of age or older
- Patient is continuing therapy [C]

AND

4 - Patient is able to swallow a capsule whole

Product Name:Koselugo

Diagnosis	Neurofibromatosis Type 1
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KOSELUGO	SELUMETINIB SULFATE CAP 10 MG	21533565500110	Brand
KOSELUGO	SELUMETINIB SULFATE CAP 25 MG	21533565500125	Brand

Approval Criteria

1 - Patient does not show evidence of disease progression while on therapy

3 . Endnotes

A. The initial authorization duration of 6 months is to allow for assessment of adverse reactions (e.g., cardiomyopathy) without interruption of therapy [1,2].
B. Inoperable plexiform neurofibromas are defined as those that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN [1].
C. It is the recommendation of the consultant that the medication should not be discontinued due to patient's age [2].

4 . References

1. Koselugo Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. January 2024.
2. Per clinical consult with oncologist, May 27, 2020.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228455
Guideline Name	Krazati (adagrasib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Krazati (adagrasib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy. This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of a clinical benefit in a confirmatory trial(s). **Colorectal Cancer (CRC)** Indicated in combination with cetuximab, for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic CRC, as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

2 . Criteria

Product Name:Krazati	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KRAZATI	ADAGRASIB TAB 200 MG	21532410000320	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Disease is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy)

Product Name:Krazati	
Diagnosis	Colorectal Cancer (CRC)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KRAZATI	ADAGRASIB TAB 200 MG	21532410000320	Brand

Approval Criteria

1 - Diagnosis of colorectal cancer (CRC)

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Tumor is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Medication is used in combination with Erbitux (cetuximab)

AND

5 - Patient has received prior treatment with ALL of the following:

- fluoropyrimidine-based chemotherapy
- oxaliplatin-based chemotherapy
- irinotecan-based chemotherapy

Product Name:Krazati	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KRAZATI	ADAGRASIB TAB 200 MG	21532410000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Krazati Prescribing Information. Mirati Therapeutics, Inc. San Diego, CA. June 2024.
2. ClinicalTrials.gov. Phase 1/2 Study of MRTX849 in Patients With Cancer Having a KRAS G12C Mutation KRYSTAL-1. Available at: https://clinicaltrials.gov/study/NCT03785249. Accessed July 8, 2024.
3. The NCCN Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. V 4.2024 – July 3, 2024. Accessed July 8, 2024.
4. The NCCN Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. V 3.2024 – July 3, 2024. Accessed July 8, 2024.

Prior Authorization Guideline

Guideline ID	GL-228457
Guideline Name	Kyprolis (carfilzomib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Kyprolis (carfilzomib)
Multiple myeloma - combination therapy Indicated in combination with dexamethasone or with lenalidomide plus dexamethasone or daratumumab plus dexamethasone or daratumumab and hyaluronidase-fihj plus dexamethasone, or isatuximab plus dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. **Multiple myeloma - monotherapy** Indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

2 . Criteria

Product Name:Kyprolis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KYPROLIS	CARFILZOMIB FOR INJ 60 MG	21536025002120	Brand
KYPROLIS	CARFILZOMIB FOR INJ 10 MG	21536025002105	Brand
KYPROLIS	CARFILZOMIB FOR INJ 30 MG	21536025002110	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma (MM)

AND

2 - Disease is relapsed or refractory

AND

3 - Patient has received at least one prior therapy for MM

Product Name:Kyprolis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KYPROLIS	CARFILZOMIB FOR INJ 60 MG	21536025002120	Brand
KYPROLIS	CARFILZOMIB FOR INJ 10 MG	21536025002105	Brand
KYPROLIS	CARFILZOMIB FOR INJ 30 MG	21536025002110	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Kyprolis Prescribing Information. Onyx Pharmaceuticals, Inc. Thousand Oaks, CA. June 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Multiple Myeloma v5.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf. Accessed July 20, 2022.

Prior Authorization Guideline

Guideline ID	GL-228677
Guideline Name	Lambert-Eaton Myasthenic Syndrome (LEMS) Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Firdapse (amifampridine phosphate)
Lambert-Eaton Myasthenic Syndrome (LEMS) Indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years of age and older.

2 . Criteria

Product Name:Firdapse	
Approval Length	3 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FIRDAPSE	AMIFAMPRIDINE PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	76000012100320	Brand

Approval Criteria

1 - Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

AND

2 - Documentation of symptomatic LEMS that interfere with daily functions (e.g., difficulty climbing stairs, walking up steep hills)

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Firdapse	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FIRDAPSE	AMIFAMPRIDINE PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	76000012100320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in dynamometry, Timed 25-Foot Walk Test, Timed Up and Go Test)

Product Name:Firdapse	
Approval Length	3 Month(s) [A]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
FIRDAPSE	AMIFAMPRIDINE PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	76000012100320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

AND

2 - Submission of medical records (e.g., chart notes) documenting symptomatic LEMS that interfere with daily functions (e.g., difficulty climbing stairs, walking up steep hills)

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. Per clinical consultation and P&T committee recommendation, it is appropriate to check for positive clinical response earlier due to the drug's rapid onset of action. [2]

4 . References

1. Firdapse Prescribing Information. Catalyst Pharmaceuticals, Inc. Coral Gables, FL. May 2024.
2. Per clinical consult with neurologist. January 18, 2019.

Lazcluze (lazertinib)

Prior Authorization Guideline

Guideline ID	GL-233297
Guideline Name	Lazcluze (lazertinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/16/2024
P&T Revision Date:	

1 . Indications

Drug Name: Lazcluze (lazertinib)
Non-small cell lung cancer (NSCLC) Indicated in combination with amivantamab, for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.

2 . Criteria

Product Name:Lazcluze	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LAZCLUZE	LAZERTINIB MESYLATE TAB 80 MG	21360048300320	Brand
LAZCLUZE	LAZERTINIB MESYLATE TAB 240 MG	21360048300340	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Used as first line treatment of NSCLC

AND

4 - Used in combination with Rybrevant (amivantamab)

AND

5 - Presence of epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations as detected by a U.S. Food and Drug Administration (FDA) approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Lazcluze

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LAZCLUZE	LAZERTINIB MESYLATE TAB 80 MG	21360048300320	Brand
LAZCLUZE	LAZERTINIB MESYLATE TAB 240 MG	21360048300340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Lazcluze Prescribing Information. Janssen Biotech, Inc. Horsham, PA. August 2024.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-233240
Guideline Name	Lenvima (lenvatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	4/14/2015
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Lenvima (lenvatinib)
Differentiated Thyroid Carcinoma Indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC). **Renal Cell Carcinoma** 1) Indicated for use in combination with pembrolizumab, for the first line treatment of adult patients with advanced renal cell carcinoma (RCC). 2) Indicated for use in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy. **Hepatocellular Carcinoma** Indicated for the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC). **Endometrial Carcinoma** In combination with pembrolizumab, is indicated for the treatment of patients with advanced endometrial carcinoma (EC) that is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or not microsatellite instability-high (MSI-

H), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation

2 . Criteria

Product Name:Lenvima	
Diagnosis	Differentiated thyroid cancer (DTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LENVIMA 4 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)	2133505420B210	Brand
LENVIMA 8 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)	2133505420B215	Brand
LENVIMA 10 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)	2133505420B220	Brand
LENVIMA 12MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)	2133505420B223	Brand
LENVIMA 20 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)	2133505420B230	Brand
LENVIMA 14 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)	2133505420B240	Brand
LENVIMA 18 MG DAILY DOSE	LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE)	2133505420B244	Brand
LENVIMA 24 MG DAILY DOSE	LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE)	2133505420B250	Brand

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC) [A]

Product Name:Lenvima	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LENVIMA 4 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)	2133505420B210	Brand
LENVIMA 8 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)	2133505420B215	Brand
LENVIMA 10 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)	2133505420B220	Brand
LENVIMA 12MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)	2133505420B223	Brand
LENVIMA 20 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)	2133505420B230	Brand
LENVIMA 14 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)	2133505420B240	Brand
LENVIMA 18 MG DAILY DOSE	LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE)	2133505420B244	Brand
LENVIMA 24 MG DAILY DOSE	LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE)	2133505420B250	Brand

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following:

2.1 Both of the following*:

- Used as first-line treatment
- Used in combination with Keytruda (pembrolizumab)

OR

2.2 Both of the following*:

- Treatment follows one prior anti-angiogenic therapy [e.g., Inlyta (axitinib), Votrient (pazopanib), Nexavar (sorafenib), Sutent (sunitinib)]
- Used in combination with Afinitor (everolimus)

Notes	*Criterion is part of FDA-approved label.

Product Name:Lenvima	
Diagnosis	Hepatocellular Carcinoma (HCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LENVIMA 4 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)	2133505420B210	Brand
LENVIMA 8 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)	2133505420B215	Brand

LENVIMA 10 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)	2133505420B220	Brand
LENVIMA 12MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)	2133505420B223	Brand
LENVIMA 20 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)	2133505420B230	Brand
LENVIMA 14 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)	2133505420B240	Brand
LENVIMA 18 MG DAILY DOSE	LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE)	2133505420B244	Brand
LENVIMA 24 MG DAILY DOSE	LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE)	2133505420B250	Brand

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

Product Name:Lenvima	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LENVIMA 4 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)	2133505420B210	Brand
LENVIMA 8 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)	2133505420B215	Brand
LENVIMA 10 MG	LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)	2133505420B220	Brand

DAILY DOSE			
LENVIMA 12MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)	2133505420B223	Brand
LENVIMA 20 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)	2133505420B230	Brand
LENVIMA 14 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)	2133505420B240	Brand
LENVIMA 18 MG DAILY DOSE	LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE)	2133505420B244	Brand
LENVIMA 24 MG DAILY DOSE	LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE)	2133505420B250	Brand

Approval Criteria

1 - Diagnosis of advanced endometrial carcinoma that is mismatch repair proficient (pMMR), or not microsatellite instability-high (MSI-H), as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

2 - Patient has disease progression following systemic therapy

AND

3 - Used in combination with Keytruda (pembrolizumab) therapy

AND

4 - Patient is not a candidate for curative surgery or radiation

Product Name:Lenvima	
Diagnosis	All indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LENVIMA 4 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)	2133505420B210	Brand
LENVIMA 8 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)	2133505420B215	Brand
LENVIMA 10 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)	2133505420B220	Brand
LENVIMA 12MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)	2133505420B223	Brand
LENVIMA 20 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)	2133505420B230	Brand
LENVIMA 14 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)	2133505420B240	Brand
LENVIMA 18 MG DAILY DOSE	LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE)	2133505420B244	Brand
LENVIMA 24 MG DAILY DOSE	LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE)	2133505420B250	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Differentiated thyroid carcinoma includes papillary carcinoma, follicular carcinoma, Hurthle cell carcinoma, and poorly differentiated carcinoma. [2]

4 . References

1. Lenvima Prescribing Information. Eisai Inc. Nutley, NJ. June 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 24, 2024.
3. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. v3.2018. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed September 5, 2018.
4. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Kidney Cancer. V2.2025. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed October 24, 2024

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228679
Guideline Name	Leqvio (inclisiran) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Leqvio (inclisiran) injection, for subcutaneous use
Primary Hyperlipidemia Indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).

2 . Criteria

Product Name:Leqvio	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)]
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEQVIO	INCLISIRAN SODIUM SUBCUTANEOUS SOLN PREF SYR 284 MG/1.5ML	3935604040E520	Brand

Approval Criteria

1 - One of the following diagnoses:

- Heterozygous familial hypercholesterolemia (HeFH)
- Atherosclerotic cardiovascular disease (ASCVD)
- Primary hyperlipidemia

AND

2 - One of the following: [4]

- Patient has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
- Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
- Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following:

- Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy
- Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Patient has been receiving at least 12 consecutive weeks of Repatha therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

4.1.2 Despite adherence to Repatha therapy, patient has been unable to achieve LDL-C goal as evidenced by one of the following within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL with ASCVD [7]
- LDL-C greater than or equal to 70 mg/dL without ASCVD [7]

OR

4.2 Patient is unable to maintain adherence to Repatha therapy due to one of the following:

- Manual dexterity problems (e.g., tremors, arthritis)
- Visual impairment (e.g., best-corrected visual acuity of 20/200 or worse) [6]

OR

4.3 Patient has experienced a hypersensitivity reaction, defined as angioedema, vasculitis, urticaria, to Repatha therapy

AND

5 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

6 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

Product Name:Leqvio	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEQVIO	INCLISIRAN SODIUM SUBCUTANEOUS SOLN PREF SYR 284 MG/1.5ML	3935604040E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by LDL-C reduction from baseline

AND

2 - One of the following:

- Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose
- Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient has previously received at least 12 consecutive weeks of Repatha therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.1.2 Despite adherence to Repatha therapy, patient was unable to achieve LDL-C goal as evidenced by one of the following within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL with ASCVD [7]
- LDL-C greater than or equal to 70 mg/dL without ASCVD [7]

OR

3.2 Patient continues to be unable to maintain adherence to Repatha therapy due to one of the following:

- Manual dexterity problems (e.g., tremors, arthritis)
- Visual impairment (e.g., best-corrected visual acuity of 20/200 or worse) [6]

OR

3.3 Patient has experienced a hypersensitivity reaction, defined as angioedema, vasculitis, urticaria, to Repatha therapy

AND

4 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

Product Name:Leqvio	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEQVIO	INCLISIRAN SODIUM SUBCUTANEOUS SOLN PREF SYR 284 MG/1.5ML	3935604040E520	Brand

Approval Criteria

1 - One of the following diagnoses:

- Heterozygous familial hypercholesterolemia (HeFH)
- Atherosclerotic cardiovascular disease (ASCVD)
- Primary hyperlipidemia

AND

2 - One of the following:

- Patient has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
- Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
- Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following:

- Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy
- Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

4.1 Both of the following:

4.1.1 Patient has been receiving at least 12 consecutive weeks of Repatha therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

4.1.2 Despite adherence to Repatha therapy, patient has been unable to achieve LDL-C goal as evidenced by one of the following within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL with ASCVD [7]
- LDL-C greater than or equal to 70 mg/dL without ASCVD [7]

OR

4.2 Patient is unable to maintain adherence to Repatha therapy due to one of the following:

- Manual dexterity problems (e.g., tremors, arthritis)
- Visual impairment (e.g., best-corrected visual acuity of 20/200 or worse) [6]

OR

4.3 Patient has experienced a hypersensitivity reaction, defined as angioedema, vasculitis, urticaria, to Repatha therapy

AND

5 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

6 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

Product Name:Leqvio	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)]
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEQVIO	INCLISIRAN SODIUM SUBCUTANEOUS SOLN PREF SYR 284 MG/1.5ML	3935604040E520	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C reduction from baseline

AND

2 - One of the following:

- Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose
- Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

3.1 Both of the following:

3.1.1 Patient has previously received at least 12 consecutive weeks of Repatha therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.1.2 Despite adherence to Repatha therapy, patient was unable to achieve LDL-C goal as evidenced by one of the following:

- LDL-C greater than or equal to 55 mg/dL with ASCVD [7]
- LDL-C greater than or equal to 70 mg/dL without ASCVD [7]

OR

3.2 Patient continues to be unable to maintain adherence to Repatha therapy due to one of the following:

- Manual dexterity problems (e.g., tremors, arthritis)
- Visual impairment (e.g., best-corrected visual acuity of 20/200 or worse) [6]

OR

3.3 Patient has experienced a hypersensitivity reaction, defined as angioedema, vasculitis, urticaria, to Repatha therapy

AND

4 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

3 . References

1. Leqvio prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corp. July 2023.
2. Ray KK, Wright RS, Kallend D, et al. Two phase 3 trials of inclisiran in patients with elevated LDL cholesterol. N Engl J Med. 2020;382(16):1507-1519.
3. Raal FJ, Kallend D, Ray KK, et al. Inclisiran for the Treatment of Heterozygous Familial Hypercholesterolemia. N Engl J Med. 2020;382(16):1520-1530.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.
5. Scientific Steering Committee on behalf of the Simon Broome Register Group. Risk of fatal coronary heart disease in familial hypercholesterolaemia. BMJ. 1991;303:893-6.
6. Vision Impairment and Blindness | Examination-Based Studies | Information on Data Sources | Vision and Eye Health Surveillance System | Vision Health Initiative (VHI) | CDC. www.cdc.gov. Published February 27, 2019. Accessed April 5, 2022.
7. Lloyd-Jones D, Morris P, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. J Am Coll Cardiol. 2022 Oct, 80 (14) 1366–1418. https://doi.org/10.1016/j.jacc.2022.07.006

Prior Authorization Guideline

Guideline ID	GL-228459
Guideline Name	Leukotriene Modifiers
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zyflo (zileuton)
Asthma Indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Zyflo is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. Therapy with Zyflo can be continued during acute exacerbations of asthma.
Drug Name: Zileuton extended-release
Asthma Indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Zileuton extended-release tablet is not indicated for use in the reversal of bronchospasm in acute asthma attacks. Therapy with zileuton extended-release tablet can be continued during acute exacerbations of asthma.

2 . Criteria

Product Name:Zyflo, Generic zileuton ER	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ZYFLO	ZILEUTON TAB 600 MG	44504085000330	Brand
ZILEUTON ER	ZILEUTON TAB SR 12HR 600 MG	44504085007420	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), intolerance or contraindication to at least one of the following generics:

- montelukast
- zafirlukast

3 . References

1. Zyflo [prescribing Information]. Cary, NC: Chiesi USA, Inc; January 2022.
2. Zileuton Extended-Release [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc; August 2020

Prior Authorization Guideline

Guideline ID	GL-228462
Guideline Name	Litfulo (ritlecitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Litfulo (ritlecitinib)
Alopecia Areata (AA) Indicated for the treatment of adult and adolescent patients 12 years and older with severe alopecia areata. Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

2 . Criteria

Product Name:Litfulo	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LITFULO	RITLECITINIB TOSYLATE CAP 50 MG (BASE EQUIV)	90731060100120	Brand

Approval Criteria

1 - Diagnosis of alopecia areata

AND

2 - Patient has at least 50% scalp hair loss [1, 2]

AND

3 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, trichotillomania, other scalp disease) [2]

AND

4 - Patient is 12 years of age or older

AND

5 - Prescribed by or in consultation with a dermatologist

AND

6 - Not used in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants*

Notes	*Litfulo may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Litfulo	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LITFULO	RITLECITINIB TOSYLATE CAP 50 MG (BASE EQUIV)	90731060100120	Brand

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Not used in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants*

Notes	*Litfulo may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . References

1. Litfulo Prescribing Information. Pfizer. New York, NY. June 2023.
2. King B, Zhang X, Harcha WG, et al. Efficacy and safety of ritlecitinib in adults and adolescents with alopecia areata: a randomised, double-blind, multicentre, phase 2b-3 trial. Lancet. 2023;401(10387):1518-1529.

Prior Authorization Guideline

Guideline ID	GL-233298
Guideline Name	Livdelzi (seladelpar)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/16/2024
P&T Revision Date:	

1 . Indications

Drug Name: Livdelzi (seladelpar)
Primary biliary cholangitis (PBC) Indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. This indication is approved under accelerated approval based on a reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).Limitations of Use: Use of Livdelzi is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)

2 . Criteria

Product Name:Livdelzi	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LIVDELZI	SELADELPAR LYSINE CAP 10 MG	52780070500120	Brand

Approval Criteria

1 - Diagnosis of primary biliary cholangitis (PBC) (also known as primary biliary cirrhosis)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after at least 12 consecutive months of treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) [2, A]

AND

2.1.2 Used in combination with ursodeoxycholic acid (UDCA)

OR

2.2 History of contraindication or intolerance to ursodeoxycholic acid (UDCA)

AND

3 - Requested drug will not be used in combination with Ocaliva (obeticholic acid) or Iqirvo (elafibranor)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

Product Name:Livdelzi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LIVDELZI	SELADELPAR LYSINE CAP 10 MG	52780070500120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., ALP level less than 1.67 times ULN, total bilirubin less than or equal to ULN, ALP decrease greater than or equal to 15% from baseline)

AND

2 - Requested drug will not be used in combination with Ocaliva (obeticholic acid) or Iqirvo (elafibranor)

3 . Endnotes

A. Biochemical response should be assessed after 1 year of treatment with UDCA [2]

4 . References

1. Livdelzi Prescribing Information. Gilead Sciences, Inc Foster City, CA 94404. August 2024.
2. Lindor, Keith D.*,1; Bowlus, Christopher L.2; Boyer, James3; Levy, Cynthia4; Mayo, Marlyn5. Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. Hepatology 69(1):p 394-419, January 2019. | DOI: 10.1002/hep.30145

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-229176
Guideline Name	Livmarli (maralixibat) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/18/2021
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Livmarli (maralixibat)
Alagille syndrome Indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 3 months of age and older. **Progressive Familial Intrahepatic Cholestasis (PFIC)** Indicated for the treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Limitations of use: LIVMARLI is not recommended in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in non-functional or complete absence of bile salt export pump (BSEP) protein.

2 . Criteria

Product Name:Livmarli	
Diagnosis	Alagille syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LIVMARLI	MARALIXIBAT CHLORIDE ORAL SOLN 9.5 MG/ML	52350050102020	Brand
LIVMARLI	MARALIXIBAT CHLORIDE ORAL SOLN 19 MG/ML	52350050102040	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Alagille Syndrome (ALGS)

AND

1.2 Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene [A, 2, 6]

AND

2 - Documentation of ONE of the following: [4]

- Total serum bile acid > 3x the upper limit of normal (ULN)
- Conjugated bilirubin > 1 mg/dL
- Fat soluble vitamin deficiency otherwise unexplainable
- Gammaglutamyl transpeptidase (GGT) > 3x ULN

AND

3 - Patient is experiencing moderate to severe cholestatic pruritus [4]

AND

4 - Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: [B, 2, 7]

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Patient is 3 months of age or older

AND

6 - Prescribed by or in consultation with a hepatologist or gastroenterologist

Product Name:Livmarli	
Diagnosis	Alagille syndrome
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LIVMARLI	MARALIXIBAT CHLORIDE ORAL SOLN 9.5 MG/ML	52350050102020	Brand
LIVMARLI	MARALIXIBAT CHLORIDE ORAL SOLN 19 MG/ML	52350050102040	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of Alagille Syndrome (ALGS)

AND

1.2 Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene [A, 2, 6]

AND

2 - Submission of medical records (e.g., chart notes) confirming ONE of the following: [4]

- Total serum bile acid > 3x the upper limit of normal (ULN)
- Conjugated bilirubin > 1 mg/dL
- Fat soluble vitamin deficiency otherwise unexplainable
- Gammaglutamyl transpeptidase (GGT) > 3x ULN

AND

3 - Patient is experiencing moderate to severe cholestatic pruritus [4]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: [B, 2, 7]

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Patient is 3 months of age or older

AND

6 - Prescribed by or in consultation with a hepatologist or gastroenterologist

Product Name:Livmarli	
Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LIVMARLI	MARALIXIBAT CHLORIDE ORAL SOLN 9.5 MG/ML	52350050102020	Brand
LIVMARLI	MARALIXIBAT CHLORIDE ORAL SOLN 19 MG/ML	52350050102040	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Progressive familial intrahepatic cholestasis (PFIC)

AND

1.2 Molecular genetic testing confirms mutations in the ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, or MYO5B gene [9]

AND

2 - Patient is experiencing both of the following:

- Moderate to severe pruritus
- Patient has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory

AND

3 - Patient is 12 months of age or older

AND

4 - Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus:

- Ursodeoxycholic acid (e.g., Ursodiol)

- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

Product Name:Livmarli	
Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LIVMARLI	MARALIXIBAT CHLORIDE ORAL SOLN 9.5 MG/ML	52350050102020	Brand
LIVMARLI	MARALIXIBAT CHLORIDE ORAL SOLN 19 MG/ML	52350050102040	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of Progressive familial intrahepatic cholestasis (PFIC)

AND

1.2 Molecular genetic testing confirms mutations in the ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, or MYO5B gene [9]

AND

2 - Patient is experiencing both of the following:

- Moderate to severe pruritus
- Submission of medical records (e.g., chart notes) confirming patient has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory

AND

3 - Patient is 12 months of age or older

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus:

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

Product Name:Livmarli	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LIVMARLI	MARALIXIBAT CHLORIDE ORAL SOLN 9.5 MG/ML	52350050102020	Brand

LIVMARLI	MARALIXIBAT CHLORIDE ORAL SOLN 19 MG/ML	52350050102040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduced serum bile acids, improved pruritus)

3 . Endnotes

A. Alagille Syndrome is an autosomal dominant disease with variable expressivity, caused by heterozygous mutations in either JAG1 or NOTCH2. The vast majority of cases are due to JAG1 mutations accounting for 94%, and NOTCH2 mutations in additional 2–4%. [2]
B. The management of pruritus in ALGS is challenging, and a variety of therapies are often used. These include antihistamines, rifampin, ursodeoxycholic acid, cholestyramine, naltrexone, and sertraline. Clinical experience suggests that these drugs have variable efficacy in reducing pruritus; however, no prospective clinical trials has quantified the effect of any of these therapies, either alone or in combination. [7]
C. Diagnostic testing may include liver functions tests, liver ultrasound and biopsy, and/or bile analysis. Genetic testing may be used in selected patients to confirm diagnosis and distinguish type. All 3 subtypes of PFIC have increased serum bile acid levels. [8]

4 . References

1. Livmarli Prescribing Information. Mirum Pharmaceuticals, Inc. Foster City, CA. July 2024.
2. Ayoub MD, Kamath BM. Alagille Syndrome: Diagnostic Challenges and Advances in Management. Diagnostics (Basel). 2020;10(11):907. Published 2020 Nov 6. doi:10.3390/diagnostics10110907
3. Saleh M, Kamath BM, Chitayat D. Alagille syndrome: clinical perspectives. Appl Clin Genet. 2016;9:75-82. Published 2016 Jun 30. doi:10.2147/TACG.S86420
4. ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/study/NCT02160782 Accessed October 18, 2021.
5. Emerick KM, Elias MS, Melin-Aldana H, et al. Bile composition in Alagille Syndrome and PFIC patients having Partial External Biliary Diversion. BMC Gastroenterol. 2008;8:47. Published 2008 Oct 20. doi:10.1186/1471-230X-8-47
6. Diaz-Frias J, Kondamudi NP. Alagille Syndrome. [Updated 2021 Jun 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK507827/
7. Shneider BL, Spino C, Kamath BM, et al. Placebo-Controlled Randomized Trial of an Intestinal Bile Salt Transport Inhibitor for Pruritus in Alagille Syndrome. Hepatol Commun. 2018;2(10):1184-1198.

8. www.albireopharma.com/patients-families/progressive-familial-intrahepatic-cholestasis-pfic. Accessed April 15, 2024.
9. Protocol: MRX-502. https://cdn.clinicaltrials.gov/large-docs/30/NCT03905330/Prot_000.pdf. Accessed April 16, 2024.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-233390
Guideline Name	Livtencity (maribavir)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Livtencity (maribavir)
Cytomegalovirus (CMV) infection/disease Indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

2 . Criteria

Product Name:Livtencity	
Diagnosis	CMV infection/disease

Approval Length	8 Week(s) [1]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LIVTENCITY	MARIBAVIR TAB 200 MG	12200050000320	Brand

Approval Criteria

1 - Diagnosis of cytomegalovirus (CMV) infection/disease as confirmed by one of the following methods: [2, 3]

- quantitative polymerase chain reaction (qPCR)
- CMV pp65 antigenemia

AND

2 - Patient is a recipient of one of the following:

- Hematopoietic stem cell transplant
- Solid organ transplant

AND

3 - Trial and failure of a minimum 2 weeks duration, contraindication, or intolerance to one of the following therapies at an appropriately indicated dose:

- Intravenous (IV) ganciclovir
- Oral valganciclovir
- IV foscarnet
- IV cidofovir

AND

4 - Patient is 12 years of age or older

AND

5 - Patient weighs greater than or equal to 35kg

AND

6 - Prescribed by or in consultation with a provider who specializes in one of the following areas:

- Transplant
- Infectious Disease
- Oncology

3 . References

1. Livtencity Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. March 2024.
2. Razonable RR, Humar A. Cytomegalovirus in solid organ transplant recipients—Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clinical Transplantation. 2019;33(9).
3. ClinicalTrials.gov [Internet]. U.S. National Library of Medicine. Identifier NCT02931539. Efficacy and Safety Study of Maribavir Treatment Compared to Investigator-assigned Treatment in Transplant Recipients With Cytomegalovirus (CMV) Infections That Are Refractory or Resistant to Treatment With Ganciclovir, Valganciclovir, Foscarnet, or Cidofovir; October 13, 2016. Available from: https://clinicaltrials.gov/ct2/show/NCT02931539.

4 . Revision History

Date	Notes
3/14/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-233337
Guideline Name	Long Acting Insulins - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/18/2025

1 . Indications

Drug Name: Levemir (insulin detemir)
Diabetes Mellitus Indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus. Limitations of Use: Levemir is not recommended for the treatment of diabetic ketoacidosis.
Drug Name: Tresiba (insulin degludec)
Diabetes Mellitus Indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus. Limitations of Use: Not recommended for the treatment of diabetic ketoacidosis.
Drug Name: Semglee (insulin glargine), Semglee (insulin glargine-yfgn), Insulin glargine-yfgn, Rezvoglar (insulin glargine-aglr)
Diabetes Mellitus Indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus. Limitations of use: Not recommended for the treatment of diabetic ketoacidosis.

Drug Name: Basaglar (insulin glargine)
Diabetes Mellitus Indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Limitations of use: Not recommended for the treatment of diabetic ketoacidosis.

Drug Name: Insulin degludec
Diabetes Mellitus Indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus. Limitations of use: Not recommended for the treatment of diabetic ketoacidosis.

2 . Criteria

Product Name:Levemir, Insulin degludec	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEVEMIR FLEXTOUCH	INSULIN DETEMIR SOLN PEN-INJECTOR 100 UNIT/ML	2710400600D220	Brand
LEVEMIR	INSULIN DETEMIR INJ 100 UNIT/ML	27104006002020	Brand
INSULIN DEGLUDEC FLEXTOUCH	INSULIN DEGLUDEC SOLN PEN-INJECTOR 200 UNIT/ML	2710400700D220	Brand
INSULIN DEGLUDEC	INSULIN DEGLUDEC INJ 100 UNIT/ML	27104007002020	Brand
INSULIN DEGLUDEC FLEXTOUCH	INSULIN DEGLUDEC SOLN PEN-INJECTOR 100 UNIT/ML	2710400700D210	Brand

Approval Criteria

1 - Diagnosis of diabetes mellitus

AND

2 - Trial and failure of a minimum 30 days supply, contraindication, or intolerance to one of the following:

- Insulin glargine-yfgn
- Rezvoglar (insulin glargine)

Product Name:Basaglar, Insulin Glargine, Semglee, Toujeo, Lantus	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
BASAGLAR KWIKPEN	INSULIN GLARGINE SOLN PEN-INJECTOR 100 UNIT/ML	2710400300D220	Brand
INSULIN GLARGINE SOLOSTAR	INSULIN GLARGINE SOLN PEN-INJECTOR 100 UNIT/ML	2710400300D220	Brand
BASAGLAR TEMPO PEN	INSULIN GLARGINE PEN-INJ WITH TRANSMITTER PORT 100 UNIT/ML	2710400300D222	Brand
INSULIN GLARGINE SOLOSTAR	INSULIN GLARGINE SOLN PEN-INJECTOR 300 UNIT/ML (1 UNIT DIAL)	2710400300D233	Brand
INSULIN GLARGINE MAX SOLOSTAR	INSULIN GLARGINE SOLN PEN-INJECTOR 300 UNIT/ML (2 UNIT DIAL)	2710400300D236	Brand
INSULIN GLARGINE	INSULIN GLARGINE INJ 100 UNIT/ML	27104003002020	Brand
SEMGLEE	INSULIN GLARGINE-YFGN SOLN PEN-INJECTOR 100 UNIT/ML	2710400390D220	Brand
SEMGLEE	INSULIN GLARGINE-YFGN INJ 100 UNIT/ML	27104003902020	Brand
TOUJEO SOLOSTAR	INSULIN GLARGINE SOLN PEN-INJECTOR 300 UNIT/ML (1 UNIT DIAL)	2710400300D233	Brand
LANTUS	INSULIN GLARGINE INJ 100 UNIT/ML	27104003002020	Brand
LANTUS SOLOSTAR	INSULIN GLARGINE SOLN PEN-INJECTOR 100 UNIT/ML	2710400300D220	Brand
TOUJEO MAX SOLOSTAR	INSULIN GLARGINE SOLN PEN-INJECTOR 300 UNIT/ML (2 UNIT DIAL)	2710400300D236	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of diabetes mellitus

AND

2 - Both of the following:

2.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with both of the following formulary alternatives that have the same active ingredient:

- Insulin glargine-yfgn
- Rezvoglar (insulin glargine)

AND

2.2 Submission of medical records (e.g., chart notes) confirming the formulary alternative(s) has not been effective AND valid clinical rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternative has not been shown to be effective despite having the same active ingredient

AND

3 - Submission of medical records (e.g., chart notes or paid claims confirming a minimum 30 days supply, contraindication, or intolerance to insulin degludec

Product Name:Tresiba	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TRESIBA FLEXTOUCH	INSULIN DEGLUDEC SOLN PEN-INJECTOR 100 UNIT/ML	2710400700D210	Brand
TRESIBA FLEXTOUCH	INSULIN DEGLUDEC SOLN PEN-INJECTOR 200 UNIT/ML	2710400700D220	Brand
TRESIBA	INSULIN DEGLUDEC INJ 100 UNIT/ML	27104007002020	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of diabetes mellitus

AND

2 - Both of the following:

2.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to insulin degludec

AND

2.2 Submission of medical records (e.g., chart notes) confirming insulin degludec has not been effective AND valid clinical rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternative has not been shown to be effective despite having the same active ingredient

AND

3 - Submission of medical records (e.g., chart notes) or paid claims confirming a minimum 30 days supply, contraindication, or intolerance to both of the following:

- Insulin glargine yfgn
- Rezvoglar (insulin glargine)

3 . References

1. Levemir Prescribing Information. Novo Nordisk Inc. Plainsboro, New Jersey. December 2022.
2. Tresiba Prescribing Information. Novo Nordisk Inc. Plainsboro, New Jersey. July 2022.
3. Basaglar Prescribing Information. Eli Lilly and Company. Indianapolis, IN. July 2021.
4. Semglee Prescribing Information. Mylan Specialty L.P. Morgantown, WV. October 2022.
5. Insulin Glargine-yfgn Prescribing Information. Mylan Specialty L.P. Morgantown, WV. July 2021.
6. Rezvoglar Prescribing Information. Eli Lilly and Company. Indianapolis, IN. March 2024.

4 . Revision History

Date	Notes
2/18/2025	Copied from Quartz EHB to Commercial

Prior Authorization Guideline

Guideline ID	GL-228903
Guideline Name	Long-Acting Bronchodilator Combinations - PA, ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Airduo Respiclick (fluticasone propionate and salmeterol) Inhalation Powder, Airduo Digihaler (fluticasone propionate and salmeterol) Inhalation Powder
Asthma Indicated for the treatment of asthma in patients aged 12 years and older. Airduo should be used for patients not adequately controlled on a long term asthma control medication such as an inhaled corticosteroid or whose disease warrants initiation of treatment with both an inhaled corticosteroid and long acting beta-2 adrenergic agonist (LABA). Limitations of Use: Airduo is NOT indicated for the relief of acute bronchospasm.
Drug Name: Bevespi Aerosphere (glycopyrrolate and formoterol fumarate)
Chronic Obstructive Pulmonary Disease (COPD) Indicated for the long-term, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Limitation of use: Bevespi Aerosphere is not indicated for the relief of acute bronchospasm or for the treatment of asthma.
Drug Name: Dulera (mometasone/formoterol) Inhalation Aerosol
Asthma Indicated for the treatment of asthma in patients 5 years of age and older. Dulera should be used for patients not adequately controlled on a long-term asthma-control

medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an ICS and long-acting beta-2-adrenergic agonist (LABA). Limitation of Use: Dulera is not indicated for the relief of acute bronchospasm.
Drug Name: Duaklir Pressair (aclidinium bromide and formoterol fumarate)
Chronic Obstructive Pulmonary Disease (COPD) Indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Limitations of Use: Not indicated for the relief of acute bronchospasm or for the treatment of asthma.
Drug Name: Wixela Inhub (fluticasone/salmeterol) Inhalation Powder
Asthma Indicated for twice-daily treatment of asthma in patients aged 4 years and older. Wixela Inhub should be used for patients not adequately controlled on a long-term asthma control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an ICS and long-acting beta - adrenergic agonist (LABA). Limitations of Use: Wixela Inhub is NOT indicated for the relief of acute bronchospasm **Chronic Obstructive Pulmonary Disease (COPD)** Maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Limitations of Use: Wixela Inhub is NOT indicated for the relief of acute bronchospasm.
Drug Name: Symbicort (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol, Breyna (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol
Asthma Indicated for the treatment of asthma in patients 6 years of age and older. Symbicort should be used for patients not adequately controlled on a long-term asthma-control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an inhaled corticosteroid and long-acting beta2-adrenergic agonist (LABA). **Chronic Obstructive Pulmonary Disease** Maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema. Limitations of Use: Not indicated for the relief of acute bronchospasm.

2 . Criteria

Product Name:Bevespi, Duaklir Pressair	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
BEVESPI AEROSPHERE	GLYCOPYRROLATE-FORMOTEROL FUMARATE AEROSOL 9-4.8 MCG/ACT	44209902543220	Brand
DUAKLIR PRESSAIR	ACLIDINIUM BR-FORMOTEROL FUM AERO POW BR ACT 400-12 MCG/ACT	44209902268030	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to both of the following:

- Anoro Ellipta
- Stiolto Respimat

Product Name:Brand Airduo Respiclick, Brand fluticasone propionate/salmeterol (Airduo Resplick ABA), Airduo Digihaler, Brand Advair Diskus, Brand Symbicort	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
AIRDUO RESPICLICK 55/14	FLUTICASONE-SALMETEROL AER POWDER BA 55-14 MCG/ACT	44209902708010	Generic
AIRDUO RESPICLICK 113/14	FLUTICASONE-SALMETEROL AER POWDER BA 113-14 MCG/ACT	44209902708015	Generic
AIRDUO RESPICLICK 232/14	FLUTICASONE-SALMETEROL AER POWDER BA 232-14 MCG/ACT	44209902708025	Generic
FLUTICASONE PROPIONATE/SALMETEROL	FLUTICASONE-SALMETEROL AER POWDER BA 55-14 MCG/ACT	44209902708010	Generic
FLUTICASONE PROPIONATE/SALMETEROL	FLUTICASONE-SALMETEROL AER POWDER BA 113-14 MCG/ACT	44209902708015	Generic
FLUTICASONE PROPIONATE/SALMETEROL	FLUTICASONE-SALMETEROL AER POWDER BA 232-14 MCG/ACT	44209902708025	Generic

AIRDUO DIGIHALER 55/14	FLUTICASONE-SALMETEROL AER POWDER BA 55-14 MCG/ACT W/ SENSOR	44209902718020	Brand
AIRDUO DIGIHALER 113/14	FLUTICASONE-SALMETEROL AER POWDER BA 113-14 MCG/ACT W/SENSOR	44209902718030	Brand
AIRDUO DIGIHALER 232/14	FLUTICASONE-SALMETEROL AER POWDER BA 232-14 MCG/ACT W/SENSOR	44209902718040	Brand
SYMBICORT	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 80-4.5 MCG/ACT	44209902413220	Brand
SYMBICORT	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 160-4.5 MCG/ACT	44209902413240	Brand
ADVAIR DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 100-50 MCG/ACT	44209902708020	Brand
ADVAIR DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 250-50 MCG/ACT	44209902708030	Brand
ADVAIR DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 500-50 MCG/ACT	44209902708040	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) or intolerance to any two of the following:

- Advair HFA (fluticasone/salmeterol)
- Breo Ellipta (fluticasone/vilanterol)
- Symbicort (budesonide/formoterol)^

Notes	^Brand product may be excluded, please consult client-specific resources to confirm formulary coverage. Recommend brand or generic product based on lower tier product.

Product Name:Dulera	
Approval Length	12 month(s)

Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 100-5 MCG/ACT	44209902903220	Brand
DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 200-5 MCG/ACT	44209902903240	Brand
DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 50-5 MCG/ACT	44209902903210	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Patient is 5 years of age

OR

2.2 All of the following:

2.2.1 Patient is 6 years of age to 12 years of age

AND

2.2.2 Trial and failure (of a minimum 30-day supply) or intolerance to Symbicort (budesonide/formoterol)^

AND

2.2.3 One of the following:

2.2.3.1 Trial and failure (of a minimum 30-day supply) or intolerance to Breo Ellipta (fluticasone/vilanterol)

OR

2.2.3.2 Patient requires a metered dose inhaler used with a spacer device due to one of the following:

- Physical dexterity
- Inspiratory flow
- Cognitive status

OR

2.3 Both of the following:

2.3.1 Patient is 12 years of age or older

AND

2.3.2 Trial and failure (of a minimum 30-day supply) or intolerance to any two of the following:

- Advair HFA (fluticasone/salmeterol)
- Breo Ellipta (fluticasone/vilanterol)
- Symbicort (budesonide/formoterol)^

Notes	^Brand product may be excluded, please consult client-specific resources to confirm formulary coverage. Recommend brand or generic product based on lower tier product.

Product Name:Dulera	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 100-5 MCG/ACT	44209902903220	Brand

DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 200-5 MCG/ACT	44209902903240	Brand
DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 50-5 MCG/ACT	44209902903210	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Patient is 5 years of age

OR

2.2 All of the following:

2.2.1 Patient is 6 years of age to 12 years of age

AND

2.2.2 Submission of chart notes (e.g., chart notes) or paid claims confirming trial and failure (of a minimum 30-day supply) or intolerance to Symbicort (budesonide/formoterol)^

AND

2.2.3 Submission of chart notes (e.g., chart notes) and/or paid claims confirming one of the following:

2.2.3.1 Trial and failure (of a minimum 30-day supply) or intolerance to Breo Ellipta (fluticasone/vilanterol)

OR

2.2.3.2 Patient requires a metered dose inhaler used with a spacer device due to one of the following:

- Physical dexterity
- Inspiratory flow
- Cognitive status

OR

2.3 Both of the following:

2.3.1 Patient is 12 years of age or older

AND

2.3.2 Submission of chart notes (e.g., chart notes) and/or paid claims confirming trial and failure (of a minimum 30-day supply) or intolerance to any two of the following:

- Advair HFA (fluticasone/salmeterol)
- Breo Ellipta (fluticasone/vilanterol)
- Symbicort (budesonide/formoterol)^

Notes	^Brand product may be excluded, please consult client-specific resources to confirm formulary coverage. Recommend brand or generic product based on lower tier product.

Product Name:Generic budesonide/formoterol, Breyna	
Approval Length	12 month(s)
Guideline Type	Prior Authorization, Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
BUDESONIDE/FORMOTEROL FUMARATE DIHYDRATE	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 80-4.5 MCG/ACT	44209902413220	Generic
BREYNA	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 80-4.5 MCG/ACT	44209902413220	Generic
BUDESONIDE/FORMOTEROL FUMARATE DIHYDRATE	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 160-4.5 MCG/ACT	44209902413240	Generic

BREYNA	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 160-4.5 MCG/ACT	44209902413240	Generic

Approval Criteria

1 - One of the following:

1.1 Requested drug is FDA-approved for the condition being treated

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming at least 6 months of use of brand Symbicort within the previous 365 days

AND

3 - Justification provided for why the generic is expected to provide benefit when brand Symbicort has not been shown to be effective

Product Name:Generic fluticasone/salmeterol powder, Wixela Inhub	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
FLUTICASONE PROPIONATE/SALMETEROL DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 100-50 MCG/DOSE	44209902708020	Generic
WIXELA INHUB	FLUTICASONE-SALMETEROL AER POWDER BA 100-50 MCG/DOSE	44209902708020	Generic
FLUTICASONE PROPIONATE/SALMETEROL	FLUTICASONE-SALMETEROL AER POWDER BA 100-50 MCG/DOSE	44209902708020	Generic

FLUTICASONE PROPIONATE/SALMETEROL DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 250-50 MCG/DOSE	44209902708030	Generic
WIXELA INHUB	FLUTICASONE-SALMETEROL AER POWDER BA 250-50 MCG/DOSE	44209902708030	Generic
FLUTICASONE PROPIONATE/SALMETEROL	FLUTICASONE-SALMETEROL AER POWDER BA 250-50 MCG/DOSE	44209902708030	Generic
FLUTICASONE PROPIONATE/SALMETEROL DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 500-50 MCG/DOSE	44209902708040	Generic
WIXELA INHUB	FLUTICASONE-SALMETEROL AER POWDER BA 500-50 MCG/DOSE	44209902708040	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) or intolerance to one of the following:

- Advair HFA (fluticasone/salmeterol)
- Breo Ellipta (fluticasone/vilanterol)
- Brand Symbicort

3 . References

1. Dulera Prescribing Information. Merck & Co., Inc. Whitehouse, NJ. March 2023.
2. Bevespi Aerosphere Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. March 2023.
3. Airduo Respiclick Prescribing Information. Teva Respiratory, LLC. Frazer, PA. February 2024.
4. Airduo Digihaler Prescribing Information. Teva Respiratory, LLC. Frazer, PA. January 2023.
5. Duaklir Pressair Prescribing Information. Circassia Pharmaceuticals Inc. Morrisville, NC. January 2022.
6. Wixela inhub Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. August 2022

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228463
Guideline Name	Long-Acting Bronchodilators - PA, ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tudorza (aclidinium bromide)
Chronic obstructive pulmonary disease (COPD) Indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
Drug Name: Incruse Ellipta (umeclidinium inhalation)
Chronic obstructive pulmonary disease (COPD) Indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
Drug Name: Spiriva Handihaler (tiotropium bromide)
Chronic Obstructive Pulmonary Disease Indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Tiotropium bromide inhalation powder is indicated to reduce exacerbations in COPD patients.

2 . Criteria

Product Name:Tudorza Pressair, Incruse Ellipta	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TUDORZA PRESSAIR	ACLIDINIUM BROMIDE AEROSOL POWD BREATH ACTIVATED 400 MCG/ACT	44100007108020	Brand
INCRUSE ELLIPTA	UMECLIDINIUM BR AERO POWD BREATH ACT 62.5 MCG/INH (BASE EQ)	44100090208030	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), intolerance or contraindication to brand Spiriva^

Notes	^Brand product may be excluded, please consult client-specific resources to confirm formulary coverage.

Product Name:Generic tiotropium bromide capsule	
Approval Length	12 month(s)
Guideline Type	Prior Authorization, Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TIOTROPIUM BROMIDE	TIOTROPIUM BROMIDE MONOHYDRATE INHAL CAP 18 MCG (BASE EQUIV)	44100080100120	Generic

Approval Criteria

1 - One of the following:

1.1 Requested drug is FDA-approved for the condition being treated

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming at least 6 months of use of brand Spiriva Handihaler within the previous 365 days

AND

3 - Justification provided for why the generic is expected to provide benefit when brand Spiriva Handihaler has not been shown to be effective

Product Name:Brand Spiriva Handihaler	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
SPIRIVA HANDIHALER	TIOTROPIUM BROMIDE MONOHYDRATE INHAL CAP 18 MCG (BASE EQUIV)	44100080100120	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), intolerance or contraindication to generic tiotropium inhalation capsules

3 . References

1. Tudorza [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; February 2021.
2. Incruse [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2023.
3. Tiotropium Bromide Prescribing Information. Lupin Pharmaceuticals, Inc. Baltimore, MD. December 2023.
4. Spiriva Handihaler Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. January 2022.

Prior Authorization Guideline

Guideline ID	GL-228466
Guideline Name	Lonsurf (trifluridine and tipiracil)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Lonsurf (trifluridine and tipiracil)
Metastatic Colorectal Cancer Indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC), as a single agent or in combination with bevacizumab, who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an antiEGFR therapy. **Metastatic Gastric Cancer** Indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

2 . Criteria

Product Name:Lonsurf

Diagnosis	Metastatic Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LONSURF	TRIFLURIDINE-TIPIRACIL TAB 15-6.14 MG	21990002750320	Brand
LONSURF	TRIFLURIDINE-TIPIRACIL TAB 20-8.19 MG	21990002750330	Brand

Approval Criteria

1 - Diagnosis of metastatic colorectal cancer (mCRC)

AND

2 - One of the following:

2.1 Used as a single agent

OR

2.2 Used in combination with bevacizumab

AND

3 - Patient has been previously treated with both of the following:

- Fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI)
- Anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])

AND

4 - One of the following:

4.1 Patient has RAS mutant tumors

OR

4.2 Both of the following:

4.2.1 Patient has RAS wild-type tumors

AND

4.2.2 Patient has been previously treated with an anti-EGFR therapy (e.g., Vectibix [panitumumab], Erbitux [cetuximab])

Product Name:Lonsurf	
Diagnosis	Metastatic Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LONSURF	TRIFLURIDINE-TIPIRACIL TAB 15-6.14 MG	21990002750320	Brand
LONSURF	TRIFLURIDINE-TIPIRACIL TAB 20-8.19 MG	21990002750330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Lonsurf	
Diagnosis	Metastatic Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LONSURF	TRIFLURIDINE-TIPIRACIL TAB 15-6.14 MG	21990002750320	Brand
LONSURF	TRIFLURIDINE-TIPIRACIL TAB 20-8.19 MG	21990002750330	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Metastatic Gastric Cancer

OR

1.2 Diagnosis of metastatic gastroesophageal junction adenocarcinoma

AND

2 - Patient has been previously treated with two of the following:

- Fluoropyrimidine-based chemotherapy
- Platinum-based chemotherapy
- Taxane or irinotecan-based chemotherapy
- HER2/neu-targeted therapy (if appropriate)

Product Name:Lonsurf	
Diagnosis	Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LONSURF	TRIFLURIDINE-TIPIRACIL TAB 15-6.14 MG	21990002750320	Brand
LONSURF	TRIFLURIDINE-TIPIRACIL TAB 20-8.19 MG	21990002750330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Lonsurf Prescribing Information. Taiho Oncology, Inc. Princeton, NJ. August 2023.
2. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium [internet database]Available at https://www.nccn.org/professionals/drug_compendium/content/ Accessed August 8, 2024

Prior Authorization Guideline

Guideline ID	GL-228467
Guideline Name	Loqtorzi (toripalimab-tpzi)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Loqtorzi (toripalimab-tpzi)
Nasopharyngeal carcinoma (NPC) Indicated, in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or with recurrent, locally advanced NPC. Indicated, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

2 . Criteria

Product Name:Loqtorzi	
Diagnosis	Nasopharyngeal carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LOQTORZI	TORIPALIMAB-TPZI IV SOLN 240 MG/6ML (40 MG/ML)	21357970722020	Brand

Approval Criteria

1 - Diagnosis of nasopharyngeal carcinoma (NPC)

AND

2 - Disease is one of the following:

- metastatic
- recurrent and locally advanced

AND

3 - One of the following:

3.1 All of the following:

3.1.1 Loqtorzi is being used as first line NPC treatment

AND

3.1.2 Loqtorzi is being used in combination with cisplatin and gemcitabine

AND

3.1.3 Treatment duration of Loqtorzi has not exceeded a total of 24 months during the patient's lifetime

OR

3.2 Both of the following:

3.2.1 Loqtorzi is being used as recurrent NPC treatment

AND

3.2.2 Disease has progressed on or after a platinum containing chemotherapy

Product Name:Loqtorzi	
Diagnosis	Nasopharyngeal carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LOQTORZI	TORIPALIMAB-TPZI IV SOLN 240 MG/6ML (40 MG/ML)	21357970722020	Brand

Approval Criteria

1 - All of the following:

1.1 Loqtorzi is being used as first line NPC treatment

AND

1.2 Patient does not show evidence of progressive disease while on therapy

AND

1.3 Treatment duration of Loqtorzi has not exceeded a total of 24 months during the patient's lifetime

OR

2 - Both of the following:

2.1 Loqtorzi is being used as recurrent NPC treatment

AND

2.2 Patient does not show evidence of progressive disease while on therapy

3 . References

1. Loqtorzi Prescribing Information.Coherus BioSciences, Inc. Redwood City, CA. October 2023

Prior Authorization Guideline

Guideline ID	GL-228470
Guideline Name	Lorbrena (lorlatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Lorbrena (lorlatinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

2 . Criteria

Product Name:Lorbrena	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LORBRENA	LORLATINIB TAB 25 MG	21530556000320	Brand
LORBRENA	LORLATINIB TAB 100 MG	21530556000330	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - One of the following:

2.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

- Alecensa (alectinib)
- Alunbrig (brugatinib)

OR

2.2 For continuation of prior therapy

Product Name:Lorbrena	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LORBRENA	LORLATINIB TAB 25 MG	21530556000320	Brand
LORBRENA	LORLATINIB TAB 100 MG	21530556000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while therapy

3 . References

1. Lorbrena Prescribing Information. Pfizer Labs. New York, NY. April 2023.

Lucemyra (lofexidine)

Prior Authorization Guideline

Guideline ID	GL-233393
Guideline Name	Lucemyra (lofexidine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	1/16/2019
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Lucemyra (lofexidine)
Opioid withdrawal Indicated for the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

2 . Criteria

Product Name:Lucemyra	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
LUCEMYRA	LOFEXIDINE HCL TAB 0.18 MG (BASE EQUIVALENT)	62805045100315	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to clonidine

3 . References

1. Lucemyra Prescribing Information. USWM, LLC. Louisville, KY. September 2020.

4 . Revision History

Date	Notes
3/14/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-229152
Guideline Name	Lumakras (sotorasib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	8/19/2021
P&T Revision Date:	8/15/2024

1 . Indications

Drug Name: Lumakras (sotorasib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy. This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name:Lumakras

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUMAKRAS	SOTORASIB TAB 120 MG	21532480000320	Brand
LUMAKRAS	SOTORASIB TAB 320 MG	21532480000340	Brand
LUMAKRAS	SOTORASIB TAB 240 MG	21532480000330	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Presence of KRAS G12C-mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy)

Product Name:Lumakras	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUMAKRAS	SOTORASIB TAB 120 MG	21532480000320	Brand
LUMAKRAS	SOTORASIB TAB 320 MG	21532480000340	Brand
LUMAKRAS	SOTORASIB TAB 240 MG	21532480000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Lumakras [package insert]. Thousand Oaks, CA: Amgen, Inc; June 2024.
2. Skoulidis F, Li BT, Dy GK, et al. Sotorasib for lung cancers with KRAS p.G12C mutation. N Engl J Med 2021;384:2371-2381.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228681
Guideline Name	Lumizyme (alglucosidase alfa)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Lumizyme (alglucosidase alfa)
Pompe Disease Indicated for patients with Pompe disease [acid alpha-glucosidase (GAA) deficiency].

2 . Criteria

Product Name:Lumizyme	
Diagnosis	Infantile Onset Pompe Disease (IOPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUMIZYME	ALGLUCOSIDASE ALFA FOR IV SOLN 50 MG	30907715002120	Brand

Approval Criteria

1 - Diagnosis of infantile-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: [3]

1.1 Absence or deficiency (less than 1% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

OR

1.2 Molecular genetic testing confirms mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., cardiomegaly, hypotonia, etc.)

AND

3 - Patient is less than or equal to 12 months of age

Product Name:Lumizyme	
Diagnosis	Infantile Onset Pompe Disease (IOPD)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUMIZYME	ALGLUCOSIDASE ALFA FOR IV SOLN 50 MG	30907715002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Lumizyme	
Diagnosis	Late Onset Pompe Disease (LOPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUMIZYME	ALGLUCOSIDASE ALFA FOR IV SOLN 50 MG	30907715002120	Brand

Approval Criteria

1 - Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: [3, 5]

1.1 Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

OR

1.2 Molecular genetic testing confirms mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.) [A]

AND

3 - Patient is 1 year of age or older

Product Name:Lumizyme	
Diagnosis	Late Onset Pompe Disease (LOPD)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUMIZYME	ALGLUCOSIDASE ALFA FOR IV SOLN 50 MG	30907715002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. Consensus recommendation based on current clinical guidelines indicate that treatment should be started in patients with late onset Pompe disease when they become symptomatic and/or show signs of disease progression [3, 5].

4 . References

1. Lumizyme Prescribing Information. Genzyme Corporation. Cambridge, MA. March 2024.
2. Kronn DF, Day-Salvatore D, Hwu WL, et al. Management of Confirmed Newborn-Screened Patients With Pompe Disease Across the Disease Spectrum.
3. Kishani PS, Steiner RD, Bali, D. ACMG Practice Guideline. Pompe disease diagnosis and management guideline. Genet Med. 2006;8(5):267-88.
4. Diagnosing Pompe Disease (also known as Acid Maltase Deficiency). Available at: https://www.pompe.com/-/media/EMS/Conditions/RareDiseases/Brands/pompe-us/hcp/PDF/SAUSPD18042050bk1vFinal10.pdf?la=en-US and https://www.pompe.com/-/media/EMS/Conditions/RareDiseases/Brands/pompe-us/hcp/PDF/SAUSPD18042050bj1vFinal10.pdf?la=en-US. Accessed May 12, 2020.
5. Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Rev Neurol 2012; 54 (8): 497-507.

Prior Authorization Guideline

Guideline ID	GL-228471
Guideline Name	Lupkynis (voclosporin) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Lupkynis (voclosporin)
Lupus Nephritis Indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN). Limitations of Use: Safety and efficacy of Lupkynis have not been established in combination with cyclophosphamide. Use of Lupkynis is not recommended in this situation.

2 . Criteria

Product Name:Lupkynis	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUPKYNIS	VOCLOSPORIN CAP 7.9 MG	99402080000120	Brand

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Used in combination with immunosuppressive therapy (e.g., mycophenolate mofetil, methylprednisolone)

AND

3 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Rheumatologist

Product Name:Lupkynis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUPKYNIS	VOCLOSPORIN CAP 7.9 MG	99402080000120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Lupkynis	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LUPKYNIS	VOCLOSPORIN CAP 7.9 MG	99402080000120	Brand

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Used in combination with immunosuppressive therapy (e.g., mycophenolate mofetil, methylprednisolone)

AND

3 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Rheumatologist

3 . References

1. Lupkynis Prescribing Information. Aurinia Pharma U.S., Inc. Rockville, MD. January 2021.

Prior Authorization Guideline

Guideline ID	GL-228905
Guideline Name	Lynparza (olaparib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Lynparza (olaparib)
First-line maintenance treatment of BRCA-mutated advanced ovarian cancer Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAmor sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. **Maintenance treatment of BRCA-mutated recurrent ovarian cancer** Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. **First-line maintenance treatment of HRD-positive advanced ovarian cancer in combination with bevacizumab** Indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency

(HRD)-positive status defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Germline BRCA-mutated HER2-negative high risk early breast cancer Indicated for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCA-mutated, HER2-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Germline BRCA-mutated HER2-negative metastatic breast cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious gBRCA-mutated, HER2-negative metastatic breast cancer, who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

First-line maintenance treatment of germline BRCA-mutated metastatic pancreatic adenocarcinoma Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

HRR gene-mutated metastatic castration-resistant prostate cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) Indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

2 . Criteria

Product Name:Lynparza	
Diagnosis	Epithelial ovarian, Fallopian tube, or Primary peritoneal cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYNPARZA	OLAPARIB TAB 100 MG	21535560000330	Brand
LYNPARZA	OLAPARIB TAB 150 MG	21535560000340	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

Product Name:Lynparza	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYNPARZA	OLAPARIB TAB 100 MG	21535560000330	Brand
LYNPARZA	OLAPARIB TAB 150 MG	21535560000340	Brand

Approval Criteria

1 - Diagnosis of breast cancer

Product Name:Lynparza	
Diagnosis	Pancreatic adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYNPARZA	OLAPARIB TAB 100 MG	21535560000330	Brand
LYNPARZA	OLAPARIB TAB 150 MG	21535560000340	Brand

Approval Criteria

1 - Diagnosis pancreatic adenocarcinoma

Product Name:Lynparza	
Diagnosis	Metastatic castration-resistant prostate cancer (mCRPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYNPARZA	OLAPARIB TAB 100 MG	21535560000330	Brand
LYNPARZA	OLAPARIB TAB 150 MG	21535560000340	Brand

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)

AND

2 - Presence of a deleterious or suspected deleterious BRCA-mutation or homologous recombination repair (HRR) gene mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - For BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC), Lynparza is used in combination with abiraterone and one of the following:

- prednisone
- prednisolone

Product Name:Lynparza	
Diagnosis	All Indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYNPARZA	OLAPARIB TAB 100 MG	21535560000330	Brand
LYNPARZA	OLAPARIB TAB 150 MG	21535560000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Lynparza Tablets prescribing information. AstraZeneca Pharmaceuticals LP, Inc. Wilmington, DE. November 2023.
2. Lynparza FDA Medical Review. http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206162Orig1s000MedR.pdf. Accessed on June 12, 2015.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 9, 2021.
4. Robson M, Im SA, Senkus E, et al. Olaparib for Metastatic Breast Cancer in Patients with a Germline BRCA Mutation. N Engl J Med. 2017 Aug 10;377(6):523-533
5. U.S. Food and Drug Administration [website]: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm Accessed 3/7/2018

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229179
Guideline Name	Lytgobi (futibatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	12/14/2022
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Lytgobi (futibatinib)
Cholangiocarcinoma Indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name:Lytgobi

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYTGOBI	FUTIBATINIB TAB THERAPY PACK 4 MG (12 MG DAILY DOSE)	2153222800B720	Brand
LYTGOBI	FUTIBATINIB TAB THERAPY PACK 4 MG (16 MG DAILY DOSE)	2153222800B725	Brand
LYTGOBI	FUTIBATINIB TAB THERAPY PACK 4 MG (20 MG DAILY DOSE)	2153222800B730	Brand

Approval Criteria

1 - Diagnosis of intrahepatic cholangiocarcinoma

AND

2 - Disease is one of the following:

- Unresectable
- Locally advanced
- Metastatic

AND

3 - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements [A]

AND

4 - Patient has been previously treated (e.g., chemotherapy)

Product Name:Lytgobi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYTGOBI	FUTIBATINIB TAB THERAPY PACK 4 MG (12 MG DAILY DOSE)	2153222800B720	Brand
LYTGOBI	FUTIBATINIB TAB THERAPY PACK 4 MG (16 MG DAILY DOSE)	2153222800B725	Brand
LYTGOBI	FUTIBATINIB TAB THERAPY PACK 4 MG (20 MG DAILY DOSE)	2153222800B730	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. An FDA-approved test for detection of FGFR2 gene fusions or other rearrangements in patients with unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma for selecting patients for treatment with LYTGOBI is not available. The presence of FGFR2 fusions or other rearrangements was determined using next generation sequencing (NGS) testing. [1]

4 . References

1. Lytgobi Prescribing Information. Taiho Oncology, Inc. Princeton, NJ. April 2024.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228906
Guideline Name	Mavyret (glecaprevir/pibrentasvir)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Mavyret (glecaprevir/pibrentasvir)
Chronic Hepatitis C (CHC) Indicated for the treatment of adult and pediatric patients 3 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). Indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

2 . Criteria

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Naïve; without Decompensated Cirrhosis

Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is treatment-naive

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)

Diagnosis	Chronic Hepatitis C - Genotype 1; Treatment-Experienced (Prior failure to an NS3/4A Protease Inhibitor); without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient has experienced failure with a previous treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1; Treatment-Experienced (Prior failure to an NS5A Inhibitor); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 3; Treatment-Experienced (Interferon- or Sovaldi-based Regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 3

AND

2 - Patient has experienced treatment failure with a previous treatment regimen that included interferon, peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); without Cirrhosis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without cirrhosis

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); with Compensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient has compensated cirrhosis (e.g., Child-Pugh Class A)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Sovaldi-based regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous treatment regimen that included Sovaldi (sofosbuvir)

AND

3 - Patient has had no previous treatment experience with an HCV NS3/4A protease inhibitor inclusive combination direct acting antiviral regimen (e.g., Zepatier [elbasvir/grazoprevir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Mavyret); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Mavyret (glecaprevir/pibrentasvir) [2]

AND

3 - Used in combination with Sovaldi (sofosbuvir) and ribavirin [2]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Vosevi); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [2]

AND

3 - Used in combination with Sovaldi (sofosbuvir) and ribavirin [2]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 Post-Liver or Kidney Transplant; Treatment-Naive or Treatment-Experienced (Non-Direct-Acting Antiviral); without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has had a liver or kidney transplant [2]

AND

3 - One of the following:

- Patient is treatment-naive
- Patient has previously received non-direct-acting antiviral treatment (e.g., peginterferon)

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; HCV-Uninfected Recipients of a Liver Transplant from HCV-Viremic Donors; without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Both of the following [2]:

- Patient was not infected with HCV prior to receiving a liver transplant
- Patient received a liver transplant from a donor with a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; HCV-Uninfected Recipients of Non-Liver Organ Transplant from HCV-Viremic Donors; without Decompensated Cirrhosis; within First Week After Transplant
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Both of the following [2]:

- Patient was not infected with HCV prior to receiving a non-liver organ transplant
- Patient received a non-liver organ transplant from a donor with a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Treatment initiation will occur no later than the first week after transplant

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; HCV-Uninfected Recipients of Non-Liver Organ Transplant from HCV-Viremic Donors; without Decompensated Cirrhosis; beyond First Week After Transplant
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Both of the following [2]:

- Patient was not infected with HCV prior to receiving a non-liver organ transplant
- Patient received a non-liver organ transplant from a donor with a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Treatment initiation will occur beyond the first week after transplant

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

3 . References

1. Mavyret Prescribing Information. Abbvie Inc. North Chicago, IL. October 2023.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Mekinist (trametinib)

Prior Authorization Guideline

Guideline ID	GL-228907
Guideline Name	Mekinist (trametinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Mekinist (trametinib)
BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma Indicated, as a single agent in BRAF-inhibitor treatment-naïve patients or in combination with dabrafenib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. **BRAF V600E mutation-positive metastatic non-small cell lung cancer** Indicated, in combination with dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer with BRAF V600E mutation as detected by an FDA-approved test. **Adjuvant treatment of BRAF V600E or V600K mutation-positive melanoma** Indicated, in combination with dabrafenib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node (s), following complete resection. **BRAF V600E mutation-positive locally advanced or metastatic anaplastic thyroid cancer** Indicated, in combination with dabrafenib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional options.

BRAF V600E mutation-positive unresectable or metastatic solid tumors Indicated, in combination with dabrafenib, for the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

BRAF V600E mutation-positive low-grade glioma Indicated, in combination with dabrafenib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

Limitations of Use MEKINIST is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition.

2 . Criteria

Product Name:Mekinist	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - One of the following diagnoses: [2]

- Unresectable melanoma
- Metastatic melanoma

AND

2 - Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

Product Name:Mekinist	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Mekinist	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand

MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer

AND

2 - Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name:Mekinist	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Mekinist	
Diagnosis	Adjuvant treatment for melanoma
Approval Length	12 Month [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Cancer is BRAF V600E mutation or V600K mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Involvement of lymph nodes following complete resection [2]

AND

4 - Used as adjunctive therapy

AND

5 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name:Mekinist	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) [4]

AND

2 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Cancer may not be treated with standard locoregional treatment options

AND

4 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name:Mekinist	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Mekinist	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Patient is 1 year of age or older

AND

3 - Disease is one of the following:

- unresectable
- metastatic

AND

4 - Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options

AND

5 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name:Mekinist	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand

MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Mekinist	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Diagnosis of low-grade glioma

AND

2 - Patient is 1 year of age or older

AND

3 - Patient requires systemic therapy

AND

4 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name:Mekinist	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. The recommended dosage of MEKINIST is 2 mg orally taken once daily in combination with dabrafenib until disease recurrence or unacceptable toxicity for up to 1 year for the adjuvant treatment of melanoma [1].

4 . References

1. Mekinist Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2023.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Melanoma v.3.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed February 11, 2024.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer v.2.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 11, 2024.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma v.1.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed February 11 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228473
Guideline Name	Mektovi (binimetinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Mektovi (binimetinib)
BRAF V600E or V600K unresectable or metastatic melanoma Indicated in combination with Braftovi (encorafenib), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test. **Non-Small Cell Lung Cancer (NSCLC)** Indicated in combination with Braftovi (encorafenib) for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test.

2 . Criteria

Product Name:Mektovi	
Diagnosis	Melanoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKTOVI	BINIMETINIB TAB 15 MG	21533520000320	Brand

Approval Criteria

1 - One of the following diagnoses:

- Unresectable melanoma
- Metastatic melanoma

AND

2 - Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Used in combination with encorafenib

AND

4 - One of the following:

4.1 Trial and failure, contraindication or intolerance to one of the following:

- Cotellic
- Mekinist

OR

4.2 For continuation of prior therapy

Product Name:Mektovi	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKTOVI	BINIMETINIB TAB 15 MG	21533520000320	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Used in combination with encorafenib

Product Name:Mektovi	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKTOVI	BINIMETINIB TAB 15 MG	21533520000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Mektovi Prescribing Information. Array Biopharma Inc. Boulder, CO. October 2023.
2. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: Melanoma: Cutaneous v.2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed May 31, 2024.

Prior Authorization Guideline

Guideline ID	GL-228683
Guideline Name	Mepsevii (vestronidase alfa-vjbk)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Mepsevii (vestronidase alfa-vjbk)
Mucopolysaccharidosis (MPS VII, Sly Syndrome) Indicated for the treatment of Mucopolysaccharidosis (MPS VII, Sly Syndrome) in pediatric and adult patients. Limitations of use: The effect of Mepsevii on the central nervous system manifestations of MPS VII has not been determined.

2 . Criteria

Product Name:Mepsevii	
Diagnosis	Mucopolysaccharidosis (MPS VII, Sly Syndrome)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEPSEVII	VESTRONIDASE ALFA-VJBK IV SOLN 10 MG/5ML (2 MG/ML)	30907680202020	Brand

Approval Criteria

1 - Diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome)

Product Name:Mepsevii	
Diagnosis	Mucopolysaccharidosis (MPS VII, Sly Syndrome)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEPSEVII	VESTRONIDASE ALFA-VJBK IV SOLN 10 MG/5ML (2 MG/ML)	30907680202020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Mepsevii Prescribing Information. Ultragenyx Pharmaceutical Inc. Novato CA. December 2020.

Prior Authorization Guideline

Guideline ID	GL-228475
Guideline Name	Methotrexate Auto-injectors
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Otrexup (methotrexate injection)
Rheumatoid Arthritis Indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) (ACR criteria), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs). **Polyarticular Juvenile Idiopathic Arthritis** Indicated in the management of children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs). **Psoriasis** Indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis “flare” is not due to an undiagnosed concomitant disease affecting immune responses. **Limitation of Use** Not indicated for the treatment of neoplastic diseases.

Drug Name: Rasuvo (methotrexate injection)
Rheumatoid Arthritis Indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) (ACR criteria), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs). **Polyarticular Juvenile Idiopathic Arthritis** Indicated in the management of children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs). **Psoriasis** Indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis "flare" is not due to an undiagnosed concomitant disease affecting immune responses. **Limitation of Use** Not indicated for the treatment of neoplastic diseases.
Drug Name: Reditrex (methotrexate injection)
Rheumatoid Arthritis Indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) (ACR criteria) who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs). **Polyarticular Juvenile Idiopathic Arthritis** Indicated in the management of children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs). **Psoriasis** Indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis "flare" is not due to an undiagnosed concomitant disease affecting immune responses. **Limitation of Use** Not indicated for the treatment of neoplastic diseases.

2 . Criteria

Product Name:Rasuvo	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 7.5 MG/0.15ML	6625005000D510	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 10 MG/0.2ML	6625005000D512	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 12.5 MG/0.25ML	6625005000D517	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 15 MG/0.3ML	6625005000D519	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 17.5 MG/0.35ML	6625005000D522	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 20 MG/0.4ML	6625005000D525	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 22.5 MG/0.45ML	6625005000D527	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.5ML	6625005000D535	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 30 MG/0.6ML	6625005000D545	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of severe, active rheumatoid arthritis

AND

1.1.2 Prescribed by or in consultation with a rheumatologist

OR

1.2 Both of the following:

1.2.1 Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

1.2.2 Prescribed by or in consultation with a rheumatologist

OR

1.3 Both of the following:

1.3.1 Diagnosis of severe psoriasis

AND

1.3.2 Prescribed by or in consultation with a dermatologist

AND

2 - Trial and failure or intolerance to oral methotrexate

Product Name:Otrexup, Reditrex	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 10MG/0.4ML	6625005000D515	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 15MG/0.4ML	6625005000D520	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 20MG/0.4ML	6625005000D525	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 25MG/0.4ML	6625005000D530	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 12.5 MG/0.4ML	6625005000D518	Brand

OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 17.5 MG/0.4ML	6625005000D523	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 22.5 MG/0.4ML	6625005000D528	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 7.5 MG/0.3ML	6625005000E508	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 10 MG/0.4ML	6625005000E510	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 12.5 MG/0.5ML	6625005000E512	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 15 MG/0.6ML	6625005000E515	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 17.5 MG/0.7ML	6625005000E522	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 20 MG/0.8ML	6625005000E526	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 22.5 MG/0.9ML	6625005000E532	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 25 MG/ML	6625005000E536	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of severe, active rheumatoid arthritis

AND

1.1.2 Prescribed by or in consultation with a rheumatologist

OR

1.2 Both of the following:

1.2.1 Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

1.2.2 Prescribed by or in consultation with a rheumatologist

OR

1.3 Both of the following:

1.3.1 Diagnosis of severe psoriasis

AND

1.3.2 Prescribed by or in consultation with a dermatologist

AND

2 - Trial and failure or intolerance to both of the following:

- Oral methotrexate
- Rasuvo

Product Name:Otrexup, Rasuvo, Reditrex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 10MG/0.4ML	6625005000D515	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 15MG/0.4ML	6625005000D520	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 20MG/0.4ML	6625005000D525	Brand

OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 25MG/0.4ML	6625005000D530	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 7.5 MG/0.15ML	6625005000D510	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 10 MG/0.2ML	6625005000D512	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 12.5 MG/0.25ML	6625005000D517	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 15 MG/0.3ML	6625005000D519	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 17.5 MG/0.35ML	6625005000D522	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 20 MG/0.4ML	6625005000D525	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 22.5 MG/0.45ML	6625005000D527	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.5ML	6625005000D535	Brand
RASUVO	METHOTREXATE SOLN PF AUTO-INJECTOR 30 MG/0.6ML	6625005000D545	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 12.5 MG/0.4ML	6625005000D518	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 17.5 MG/0.4ML	6625005000D523	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 22.5 MG/0.4ML	6625005000D528	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 7.5 MG/0.3ML	6625005000E508	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 10 MG/0.4ML	6625005000E510	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 12.5 MG/0.5ML	6625005000E512	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 15 MG/0.6ML	6625005000E515	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 17.5 MG/0.7ML	6625005000E522	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 20 MG/0.8ML	6625005000E526	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 22.5 MG/0.9ML	6625005000E532	Brand
REDITREX	METHOTREXATE SOLN PREFILLED SYRINGE 25 MG/ML	6625005000E536	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 10 MG/0.4ML	6625005000D515	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 15 MG/0.4ML	6625005000D520	Brand

OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 20 MG/0.4ML	6625005000D525	Brand
OTREXUP	METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.4ML	6625005000D530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Otrexup Prescribing Information. Antares Pharma, Inc. Ewing, NJ. November 2022.
2. Rasuvo Prescribing Information, Medexus Pharma, Inc. Chicago, IL. March 2020.
3. Reditrex Prescribing Information. Cumberland Pharmaceuticals Inc., Nashville, TN. March 2023.

Prior Authorization Guideline

Guideline ID	GL-228686
Guideline Name	Miebo (perfluorohexyloctane ophthalmic solution)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Miebo (perfluorohexyloctane ophthalmic solution)
Dry Eye Disease Indicated for the treatment of the signs and symptoms of dry eye disease.

2 . Criteria

Product Name:Miebo	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

MIEBO	PERFLUOROHEXYLOCTANE OPHTH SOLN 1.338GM/ML	86807018002020	Brand

Approval Criteria

1 - Diagnosis of dry eye disease

Product Name:Miebo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MIEBO	PERFLUOROHEXYLOCTANE OPHTH SOLN 1.338 GM/ML	86807018002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

3 . Endnotes

A. Traditional diagnostic tests include the Schirmer test, ocular surface dye staining, tear function index/fluorescein clearance test, tear break up time, tear film osmolarity, slit lamp evaluation of lid [2-4]
B. As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (e.g., emulsions, gels, ointments). Anti-inflammatory therapies (e.g., topical cyclosporine, corticosteroids), systemic omega-3 fatty acid supplements, punctal plugs, and eyeglass side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management [2-4]

4 . References

1. Miebo Prescribing Information. Bausch & Lomb Americas Inc. Bridgewater, NJ. May 2023.
2. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern. October 2018. Available at file:///C:/Users/kdekhtaw/OneDrive%20-%20UHG/Homedir/2020%20CLIENT%20LISTS/UTILIZATION%20MANAGEMENT/M/MIEBO/Dry%20Eye%20Syndrome%20Preferred%20Practice%20Pattern%202018.pdf. Accessed July 11, 2023.
3. Wood, S., Mian, S. Diagnostic Tools for Dry Eye Disease. Available at https://www.touchophthalmology.com/wp-content/uploads/sites/16/2017/01/Diagnostic-Tools-for-Dry-Eye-Disease_1.pdf. Accessed Nov 9. 2021.
4. Zeev, M., Miller, D, et al. Diagnosis of dry eye disease and emerging technologies. Clin Ophthalmol 2014;8:581-590. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3964175/#b16-opth-8-581. Accessed November 9, 2021.
5. Tauber, J., Berdy, G., et al. NOV03 for Dry Eye Disease Associated with Meibomian Gland Dysfunction: Results of the Randomized Phase 3 GOBI Study. American Academy of Ophthalmology. Dec 2022: 516-524. Available at:https://www.aaojournal.org/article/S0161-6420(22)01016-8/pdf#:~:text=NOV03%2C%20a%20novel%2C%20nonaqueous%2C%20single-entity%2C%20preservative-%20free%2C%20ophthalmic,glands%20through%2024%20hours%2C%20with%20minimal%20systemic%20exposure.26. Accessed July 11, 2023.
6. Sheppard,J., Kurata, F., et al. NOV03 for Signs and Symptoms of Dry Eye Disease Associated With Meibomian Gland Dysfunction: The Randomized Phase 3 MOJAVE Study. American Journal of Ophthalmology. Mar 2023: 265-274. Available at: https://www.ajo.com/action/showPdf?pii=S0002-9394%2823%2900098-3. Accessed July 11, 2023.

Prior Authorization Guideline

Guideline ID	GL-228911
Guideline Name	Migraine Quantity Limit
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan) tablets and nasal spray, Onzetra (sumatriptan), Relpax (eletriptan), Tosymra (sumatriptan), Zembrace SymTouch (sumatriptan), Zomig (zolmitriptan) tablets, Zomig-ZMT (zolmitriptan)
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Safety and effectiveness of respective triptan therapy have not been established for cluster headache (not applicable to Zembrace SymTouch). Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with therapy, reconsider the diagnosis of migraine before therapy is administered to treat any subsequent attacks. Therapy is not indicated for the prevention of migraine attacks.
Drug Name: Axert (almotriptan)
Migraine Headaches Indicated for the acute treatment of migraine attacks in adults with a history of migraine with or without aura. Indicated for the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated). Important Limitations: Only use where a clear diagnosis of migraine has been established. If a patient has no response for the

first migraine attack treated with Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

Drug Name: Maxalt (rizatriptan), Maxalt-MLT (rizatriptan)

Migraine headaches Indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old. Limitations of Use: Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine. Maxalt is not indicated for the prevention of migraine attacks. Safety and effectiveness of Maxalt have not been established for cluster headache.

Drug Name: Migranal (dihydroergotamine mesylate)

Migraine Headaches Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

Drug Name: Treximet (sumatriptan/naproxen)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age or older. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.

Drug Name: Zomig (zolmitriptan) nasal spray

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.

Drug Name: D.H.E. 45 (dihydroergotamine mesylate) injection

Migraine Headache Indicated for the acute treatment of migraine headaches with or without aura.

Cluster Headaches Indicated for acute treatment of cluster headache episodes.
Drug Name: Imitrex (sumatriptan) injection
Migraine Headache Indicated in adults for the acute treatment of migraine, with or without aura. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of migraine headache attacks. **Cluster Headaches** Indicated in adults for the acute treatment of cluster headache. Limitations of Use: Use only if a clear diagnosis of cluster headache has been established. If a patient has no response to the first cluster headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of cluster headache attacks.
Drug Name: Trudhesa (dihydroergotamine mesylate)
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine or for the management of hemiplegic or basilar migraine
Drug Name: Nurtec ODT (rimegepant sulfate)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. **Preventive Treatment of Episodic Migraine** Indicated for the preventive treatment of episodic migraine in adults.
Drug Name: Ubrelvy (ubrogepant)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.
Drug Name: Zavzpret (zavegepant)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name:Brand Amerge, Generic naratriptan, Brand Axert, Generic almotriptan, Brand Frova, Generic frovatriptan, Brand Imitrex, Generic sumatriptan, Brand Maxalt, Generic rizatriptan, Onzetra, Brand Relpax, Generic eletriptan, Tosymra, Brand Treximet, Generic sumatriptan/naproxen, Zembrace SymTouch, Brand Zomig, Generic zolmitriptan, or Brand Zolmitriptan nasal spray	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
IMITREX STATDOSE SYSTEM	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 6 MG/0.5ML	6740607010D520	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 6 MG/0.5ML	6740607010D520	Generic
NARATRIPTAN HCL	NARATRIPTAN HCL TAB 1 MG (BASE EQUIV)	67406050100310	Generic
AMERGE	NARATRIPTAN HCL TAB 1 MG (BASE EQUIV)	67406050100310	Brand
NARATRIPTAN HCL	NARATRIPTAN HCL TAB 2.5 MG (BASE EQUIV)	67406050100320	Generic
AMERGE	NARATRIPTAN HCL TAB 2.5 MG (BASE EQUIV)	67406050100320	Brand
ALMOTRIPTAN MALATE	ALMOTRIPTAN MALATE TAB 6.25 MG	67406010100320	Generic
AXERT	ALMOTRIPTAN MALATE TAB 6.25 MG	67406010100320	Brand
ALMOTRIPTAN MALATE	ALMOTRIPTAN MALATE TAB 12.5 MG	67406010100330	Generic
AXERT	ALMOTRIPTAN MALATE TAB 12.5 MG	67406010100330	Brand
FROVA	FROVATRIPTAN SUCCINATE TAB 2.5 MG (BASE EQUIVALENT)	67406030100320	Brand
FROVATRIPTAN SUCCINATE	FROVATRIPTAN SUCCINATE TAB 2.5 MG (BASE EQUIVALENT)	67406030100320	Generic
IMITREX	SUMATRIPTAN NASAL SPRAY 5 MG/ACT	67406070002010	Generic
SUMATRIPTAN	SUMATRIPTAN NASAL SPRAY 5 MG/ACT	67406070002010	Generic
IMITREX	SUMATRIPTAN NASAL SPRAY 20 MG/ACT	67406070002040	Brand
SUMATRIPTAN	SUMATRIPTAN NASAL SPRAY 20 MG/ACT	67406070002040	Generic
IMITREX STATDOSE SYSTEM	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 4 MG/0.5ML	6740607010D510	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 4 MG/0.5ML	6740607010D510	Generic

IMITREX STATDOSE REFILL	SUMATRIPTAN SUCCINATE SOLUTION CARTRIDGE 4 MG/0.5ML	6740607010E210	Brand
SUMATRIPTAN SUCCINATE REFILL	SUMATRIPTAN SUCCINATE SOLUTION CARTRIDGE 4 MG/0.5ML	6740607010E210	Generic
IMITREX STATDOSE REFILL	SUMATRIPTAN SUCCINATE SOLUTION CARTRIDGE 6 MG/0.5ML	6740607010E220	Brand
SUMATRIPTAN SUCCINATE REFILL	SUMATRIPTAN SUCCINATE SOLUTION CARTRIDGE 6 MG/0.5ML	6740607010E220	Generic
IMITREX	SUMATRIPTAN SUCCINATE TAB 25 MG	67406070100305	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE TAB 25 MG	67406070100305	Generic
IMITREX	SUMATRIPTAN SUCCINATE TAB 50 MG	67406070100310	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE TAB 50 MG	67406070100310	Generic
IMITREX	SUMATRIPTAN SUCCINATE TAB 100 MG	67406070100320	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE TAB 100 MG	67406070100320	Generic
IMITREX	SUMATRIPTAN SUCCINATE INJ 6 MG/0.5ML	67406070102010	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE INJ 6 MG/0.5ML	67406070102010	Generic
RELPAX	ELETRIPTAN HYDROBROMIDE TAB 20 MG (BASE EQUIVALENT)	67406025100320	Brand
RELPAX	ELETRIPTAN HYDROBROMIDE TAB 40 MG (BASE EQUIVALENT)	67406025100340	Brand
RIZATRIPTAN BENZOATE	RIZATRIPTAN BENZOATE TAB 5 MG (BASE EQUIVALENT)	67406060100310	Generic
MAXALT	RIZATRIPTAN BENZOATE TAB 5 MG (BASE EQUIVALENT)	67406060100310	Brand
RIZATRIPTAN BENZOATE	RIZATRIPTAN BENZOATE TAB 10 MG (BASE EQUIVALENT)	67406060100320	Generic
MAXALT	RIZATRIPTAN BENZOATE TAB 10 MG (BASE EQUIVALENT)	67406060100320	Brand
MAXALT-MLT	RIZATRIPTAN BENZOATE ORAL DISINTEGRATING TAB 5 MG (BASE EQ)	67406060107220	Brand
RIZATRIPTAN BENZOATE ODT	RIZATRIPTAN BENZOATE ORAL DISINTEGRATING TAB 5 MG (BASE EQ)	67406060107220	Generic
MAXALT-MLT	RIZATRIPTAN BENZOATE ORAL DISINTEGRATING TAB 10 MG (BASE EQ)	67406060107230	Brand

RIZATRIPTAN BENZOATE ODT	RIZATRIPTAN BENZOATE ORAL DISINTEGRATING TAB 10 MG (BASE EQ)	67406060107230	Generic
TREXIMET	SUMATRIPTAN-NAPROXEN SODIUM TAB 85-500 MG	67992002600320	Brand
ZEMBRACE SYMTOUCH	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 3 MG/0.5ML	6740607010D505	Brand
ZOMIG	ZOLMITRIPTAN TAB 2.5 MG	67406080000320	Brand
ZOLMITRIPTAN	ZOLMITRIPTAN TAB 2.5 MG	67406080000320	Generic
ZOMIG	ZOLMITRIPTAN TAB 5 MG	67406080000330	Brand
ZOLMITRIPTAN	ZOLMITRIPTAN TAB 5 MG	67406080000330	Generic
ZOMIG	ZOLMITRIPTAN NASAL SPRAY 2.5 MG/SPRAY UNIT	67406080002010	Brand
ZOMIG NASAL SPRAY	ZOLMITRIPTAN NASAL SPRAY 5 MG/SPRAY UNIT	67406080002020	Brand
ZOMIG ZMT	ZOLMITRIPTAN ORALLY DISINTEGRATING TAB 2.5 MG	67406080007220	Brand
ZOLMITRIPTAN ODT	ZOLMITRIPTAN ORALLY DISINTEGRATING TAB 2.5 MG	67406080007220	Generic
ZOMIG ZMT	ZOLMITRIPTAN ORALLY DISINTEGRATING TAB 5 MG	67406080007230	Brand
ZOLMITRIPTAN ODT	ZOLMITRIPTAN ORALLY DISINTEGRATING TAB 5 MG	67406080007230	Generic
ONZETRA	SUMATRIPTAN SUCCINATE EXHALER POWDER 11 MG/NOSEPIECE	6740607010G420	Brand
TREXIMET	SUMATRIPTAN-NAPROXEN SODIUM TAB 10-60 MG	67992002600305	Brand
ELETRIPTAN HYDROBROMIDE	ELETRIPTAN HYDROBROMIDE TAB 20 MG (BASE EQUIVALENT)	67406025100320	Generic
ELETRIPTAN HYDROBROMIDE	ELETRIPTAN HYDROBROMIDE TAB 40 MG (BASE EQUIVALENT)	67406025100340	Generic
SUMATRIPTAN/NAPROXEN SODIUM	SUMATRIPTAN-NAPROXEN SODIUM TAB 85-500 MG	67992002600320	Generic
ZOLMITRIPTAN	ZOLMITRIPTAN NASAL SPRAY 2.5 MG/SPRAY UNIT	67406080002010	Generic
ZOLMITRIPTAN	ZOLMITRIPTAN NASAL SPRAY 5 MG/SPRAY UNIT	67406080002020	Generic
TOSYMRA	SUMATRIPTAN NASAL SPRAY 10 MG/ACT	67406070002020	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Patient is experiencing 2 or more headaches per month [10-12]

AND

3 - Patient will not be treating 15 or more headache days per month

AND

4 - Currently receiving prophylactic therapy with at least one of the following: [A, 10, 24]

- An antidepressant (i.e., Elavil [amitriptyline] or Effexor [venlafaxine])
- An anticonvulsant (i.e., Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate])
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- An angiotensin receptor blocker (i.e., Atacand [candesartan])
- An angiotensin-converting enzyme (ACE) inhibitor (i.e., lisinopril)

AND

5 - Not used in combination with another triptan-containing product

AND

6 - One of the following: [B]

6.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer's prescribing information

OR

6.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Product Name:Brand D.H.E. 45, Generic dihydroergotamine mesylate injection, Brand Migranal, Generic dihydroergotamine mesylate nasal spray, Nurtec ODT, Trudhesa, Ubrelvy, Zavzpret	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Generic
MIGRANAL	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Brand
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Generic
D.H.E. 45	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Brand
TRUDHESA	DIHYDROERGOTAMINE MESYLATE HFA NASAL AEROSOL 0.725 MG/ACT	67000030113420	Brand
UBRELVY	UBROGEPANT TAB 50 MG	67701080000320	Brand
UBRELVY	UBROGEPANT TAB 100 MG	67701080000340	Brand
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand
ZAVZPRET	ZAVEGEPANT HCL NASAL SPRAY 10 MG/ACT	67701090202020	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following: [B]

2.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer’s prescribing information

OR

2.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

3 . Endnotes

A. The American Academy of Neurology and American Headache Society support the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], candesartan, and lisinopril. [10, 25]
B. Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

4 . References

1. Amerge Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. October 2020.
2. Almotriptan Prescribing Information. Ajanta Pharma USA Inc. Bridgewater, NJ. March 2023.
3. Frova Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. August 2018.
4. Imitrex Tablets Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2020.
5. Imitrex Nasal Spray Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2017.
6. Imitrex Injection Prescribing Information. GlaxoSmithKline. Durham, NC. February 2023.
7. Maxalt/Maxalt MLT Prescribing Information. Organon LLC. Jersey City, NJ. June 2021.
8. Migranal Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2022.
9. Relpax Prescribing Information. Roerig. New York, NY. March 2020.
10. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012;78:1337-1345.
11. Silberstein SD, Holland S, Freitag F, et al. Erratum to: evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality

Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2013;80(9):871.
12. Snow V, Weiss K, Wall EM, Mottur-Pilson C; American Academy of Family Physicians; American College of Physicians-American Society of Internal Medicine. Pharmacologic management of acute attacks of migraine and prevention of migraine headache. Ann Intern Med. 2002;137:840-9.
13. Onzetra Xsail Prescribing Information. Currax Pharmaceuticals LLC. Morristown, NJ. December 2019.
14. Treximet Prescribing Information. Currax Pharmaceuticals LLC. Brentwood, TN. January 2024.
15. Zomig/Zomig ZMT Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.
16. Zomig Nasal Spray Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.
17. D.H.E. 45 Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. April 2022.
18. Loder E, Burch R, Rizzoli P. The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A Summary and Comparison with Other Recent Clinical Practice Guidelines. Headache 2012;52:930-945.
19. Zembrace SymTouch Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN. February 2021.
20. Tosymra Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN. February 2021.
21. Trudhesa Prescribing Information. Impel NeuroPharma Inc. Seattle, WA. August 2023.
22. Nurtec ODT Prescribing Information. Pfizer Inc. New York, NY April 2023.
23. Ubrelvy Prescribing Information. AbbVie Inc. North Chicago, IL. June 2023.
24. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.
25. Zavzpret Prescribing Information. Pfizer Labs. New York, NY. March 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233301
Guideline Name	Miplyffa (arimoclomol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/21/2024
P&T Revision Date:	

1 . Indications

Drug Name: Miplyffa (arimoclomol)
Niemann-Pick disease type C (NPC) Indicated for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older.

2 . Criteria

Product Name:Miplyffa	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MIPLYFFA	ARIMOCLOMOL CITRATE CAP 47 MG	62000003200120	Brand
MIPLYFFA	ARIMOCLOMOL CITRATE CAP 62 MG	62000003200130	Brand
MIPLYFFA	ARIMOCLOMOL CITRATE CAP 93 MG	62000003200140	Brand
MIPLYFFA	ARIMOCLOMOL CITRATE CAP 124 MG	62000003200150	Brand

Approval Criteria

1 - Diagnosis of Niemann-Pick disease type C (NPC)

AND

2 - Diagnosis is confirmed by one of the following:

2.1 Genetically confirmed (deoxyribonucleic acid [DNA] sequence analysis) by mutations in both alleles of NPC1 or NPC2

OR

2.2 Mutation in only one allele of NPC1 or NPC2 plus either positive filipin staining or elevated cholestane triol/oxysterols (>2 x upper limit of normal)

AND

3 - Patient has at least one neurological symptom of the disease (e.g., hearing loss, vertical supranuclear gaze palsy, ataxia, dementia, dystonia, seizures, dysarthria, or dysphagia)

AND

4 - Patient is 2 years of age or older

AND

5 - Requested drug will be used in combination with miglustat

AND

6 - Requested drug will NOT be used in combination with Aqneursa (levacetylleucine)

AND

7 - Prescribed by or in consultation with a specialist knowledgeable in the treatment of Niemann-Pick disease type C

Product Name:Miplyffa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MIPLYFFA	ARIMOCLOMOL CITRATE CAP 47 MG	62000003200120	Brand
MIPLYFFA	ARIMOCLOMOL CITRATE CAP 62 MG	62000003200130	Brand
MIPLYFFA	ARIMOCLOMOL CITRATE CAP 93 MG	62000003200140	Brand
MIPLYFFA	ARIMOCLOMOL CITRATE CAP 124 MG	62000003200150	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., slowing of disease progression, improvement in neurological symptoms of the disease)

AND

2 - Requested drug will be used in combination with miglustat

AND

3 - Requested drug will NOT be used in combination with Aqneursa (levacetylleucine)

3 . References

1. Miplyffa Prescribing Information. Zevra Therapeutics, Inc. FL 34747. September 2024.
2. Mengel E, Patterson MC, Da Riol RM et al. Efficacy and safety of arimoclomol in Niemann-Pick disease type C: Results from a double-blind, randomised, placebo-controlled, multinational phase 2/3 trial of a novel treatment. J Inherit Metab Dis. 2021 Nov;44(6):1463-1480. doi: 10.1002/jimd.12428. Epub 2021 Sep 7.
3. FDA Review: Miplyffa. Food and Drug Administration Web Site. 2024. http://www.accessdata.fda.gov. Accessed November 4, 2024

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228910
Guideline Name	Mitoxantrone
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Mitoxantrone
Multiple Sclerosis Indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (i.e., patients whose neurologic status is significantly abnormal between relapses). It is not indicated in the treatment of patients with primary progressive multiple sclerosis. **Prostate Cancer** Indicated, in combination with corticosteroids, as initial chemotherapy for the treatment of patients with pain related to advanced hormone-refractory prostate cancer. **Acute Non-Lymphocytic Leukemia (ANLL)** Indicated, in combination with other approved drug(s), in the initial therapy of ANLL in adults. This category includes myelogenous, promyelocytic, monocytic, and erythroid acute leukemias.

2 . Criteria

Product Name:Generic mitoxantrone	
Diagnosis	Multiple Sclerosis
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic

Approval Criteria

1 - Diagnosis of one of the following:

1.1 Secondary progressive multiple sclerosis: gradually worsening disability with or without superimposed relapses [2]

OR

1.2 Progressive relapsing multiple sclerosis: progression of disability from the onset with superimposed relapses [2]

OR

1.3 Worsening relapsing-remitting multiple sclerosis: neurological status remains significantly abnormal in between multiple sclerosis relapses [3]

AND

2 - Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod]): [B, 3, 11]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Neutrophil count greater than or equal to 1,500 cell/mm^3

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Generic mitoxantrone	
Diagnosis	Multiple Sclerosis
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140 mg/m^2 [1]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Generic mitoxantrone	
Diagnosis	Prostate Cancer
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic

Approval Criteria

1 - Diagnosis of advanced hormone-refractory (castration-resistant) prostate cancer

AND

2 - Used in combination with corticosteroids (e.g., prednisone, methylprednisolone) [7, 8, 10]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Neutrophil count greater than or equal to 1,500 cell/mm^3

Product Name:Generic mitoxantrone	
Diagnosis	Prostate Cancer
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140mg/m^2 [1]

Product Name:Generic mitoxantrone	
Diagnosis	Acute Non-Lymphocytic Leukemia (ANLL)
Approval Length	6 Months [5-6, A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic

Approval Criteria

1 - Diagnosis of acute non-lymphocytic leukemia (ANLL) (e.g., myelogenous, promyelocytic, monocytic, and erythroid)

AND

2 - Used in combination with other medications used for the treatment of ANLL [9, 10]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

Product Name:Generic mitoxantrone	
Diagnosis	Acute Non-Lymphocytic Leukemia (ANLL)
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140mg/m^2 [1]

3 . Endnotes

A. All patients should be carefully assessed for cardiac signs and symptoms by history and physical examination prior to start of Novantrone therapy. Left ventricular ejection fraction (LVEF) should be evaluated prior to administration of the initial dose of mitoxantrone and all subsequent doses. Mitoxantrone is recommended to be dosed once every three months. Additional doses of mitoxantrone should not be administered to multiple sclerosis patients who have experienced either a drop in LVEF to below 50% or a clinically significant reduction in LVEF during mitoxantrone therapy. [1]
B. Per 2018 American Academy of Neurology (AAN) Multiple Sclerosis (MS) guideline, mitoxantrone should not be prescribed to people with MS due to the high frequency of severe adverse effects unless the potential benefit greatly outweighs the risk. Another MS agent that has relatively more side effects include Lemtrada and its prescribing information recommends reserving use after two prior lines of therapies have been tried. Due to this, a requirement of two prior agents for Mitoxantrone would be more appropriate to align with other MS agents that have more risks than benefit. [11]

4 . References

1. Mitoxantrone Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. December 2019.
2. Hartung HP, Gonsette R, Konig N, et al. Mitoxantrone in progressive multiple sclerosis: a placebo-controlled, double-blind, randomized, mulitcentre trial. Lancet 2002;360:2018-25.

3. Marriott JJ, Miyasaki JM, Gronseth G, O'Connor PW. Evidence Report: The efficacy and safety of mitoxantrone (Novantrone) in the treatment of multiple sclerosis: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2010;74:1463-70.
4. Avasarala JR, Cross AH, Clifford DB, Singer BA, Siegal BA, Abbey EE. Rapid onset mitoxantrone-induced cardiotoxicity in secondary progressive multiple sclerosis. Mult Scler. 2003;9:59-62.
5. Ghalie RG, Edan G, Laurent M, et al. Cardiac adverse effects associated with mitoxantrone (Novantrone) therapy in patients with MS. Neurology. 2002;59:909-13.
6. Bastianello S, Pozzilli C, D'Andrea F, et al. A controlled trial of mitoxantrone in multiple sclerosis: serial MRI evaluation at one year. Can J Neurol Sci. 1994;21:266-70.
7. Petrylak DP, Tangen CM, Hussain MH, et al. Docetaxel and estramustine compared with mitoxantrone and prednisone for advanced refractory prostate cancer. N Engl J Med. 2004;351:1513-20.
8. Tannock IF, de Wit R, Berry WR, et al. Investigators. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. N Engl J Med. 2004;351:1502-12.
9. Anderson JE, Kopecky KJ, Willman CL, et al. Outcome after induction chemotherapy for older patients with acute myeloid leukemia is not improved with mitoxantrone and etoposide compared to cytarabine and daunorubicin: a Southwest Oncology Group study. Blood. 2002;100:3869-76. Epub 2002 Aug 1.
10. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed May 2, 2024.
11. Rae-Grant, A., Day, G., Marrie, R., Rabinstein, A., Cree, B., Gronseth, G., Haboubi, M., Halper, J., Hosey, J., Jones, D., Lisak, R., Pelletier, D., Potrebic, S., Sitcov, C., Sommers, R., Stachowiak, J., Getchius, T., Merillat, S. and Pringsheim, T., 2018. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology, 90(17), pp.777-788.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229181
Guideline Name	Molluscum Contagiosum Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/16/2023
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Ycanth (cantharidin solution)
Molluscum contagiosum Indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.

2 . Criteria

Product Name:Ycanth	
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CANTHARIDIN	CANTHARIDIN SOLN 0.7%	90750010002007	Brand
YCANTH	CANTHARIDIN SOLN 0.7%	90750010002007	Brand

Approval Criteria

1 - Diagnosis of molluscum contagiosum

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has single or multiple, 2- to 5-mm-diameter, flesh-colored to translucent, dome-shaped papules, some with central umbilication [2]

AND

4 - One of the following [4]:

- Patient has eczema (e.g., atopic dermatitis)
- Patient is immunocompromised
- Patient has extensive involvement or experiences bleeds, secondary infections or discomfort from the lesions

AND

5 - Lesions have not resolved within six months of diagnosis [4]

AND

6 - One of the following:

6.1 Patient is treating new lesions that have not previously been treated with Ycanth

OR

6.2 Lesions have previously been treated with Ycanth and will not exceed a total of 4 treatments of Ycanth [A]

AND

7 - Medication is not being used concurrently with other FDA approved therapies (e.g., Zelsuvmi) on the same lesion for the treatment of molluscum contagiosum [3]

AND

8 - Prescribed by or in consultation with a dermatologist

3 . Endnotes

A. Subjects' lesions were treated with either YCANTH or vehicle at intervals of approximately 21 days until complete clearance of the lesion or for a maximum of 4 applications

4 . References

1. Ycanth Prescribing Information. Verrica Pharmaceuticals Inc. West Chester, PA. July 2023.
2. American Academy of Pediatrics. Molluscum contagiosum. In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. Red Book: 2021–2024 Report of the Committee on Infectious Diseases. 32nd ed. Itasca, IL: American Academy of Pediatrics; 2021: 535-537.
3. Per clinical consult with dermatologist regarding Zelsuvmi, July 31, 2024.
4. Molluscum contagiosum: Diagnosis and treatment. www.aad.org. https://www.aad.org/public/diseases/a-z/molluscum-contagiosum-treatment

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-233291
Guideline Name	Mulpleta (lusutrombopag)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/17/2018
P&T Revision Date:	6/19/2024

1 . Indications

Drug Name: Mulpleta (lusutrombopag)
Thrombocytopenia Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

2 . Criteria

Product Name:Mulpleta	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MULPLETA	LUSUTROMBOPAG TAB 3 MG	82405045000320	Brand

Approval Criteria

1 - Diagnosis of thrombocytopenia

AND

2 - Baseline platelet count is less than 50,000/mcL

AND

3 - Patient has chronic liver disease

AND

4 - Patient is scheduled to undergo a procedure

AND

5 - Trial and failure, contraindication, or intolerance to Doptelet (avatrombopag maleate)

3 . References

1. Mulpleta Prescribing Information. Shionogi Inc. Florham Park, NJ. April 2020.

4 . Revision History

Date	Notes

1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-233271
Guideline Name	Multiple Sclerosis (MS) Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/20/2000
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Aubagio (teriflunomide), Avonex (interferon beta-1a), Bafiertam (monomethyl fumarate), Betaseron (interferon beta-1b), Briumvi (ublituximab-xiiy), Copaxone (glatiramer acetate), Extavia (interferon beta-1b), Glatopa (glatiramer acetate)
Relapsing forms of multiple sclerosis (MS) Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Kesimpta (ofatumumab), Mayzent (siponimod), Plegridy (peginterferon beta-1a), Ponvory (ponesimod), Rebif (interferon beta-1a), Vumerity (diroximel fumarate)
Relapsing forms of multiple sclerosis (MS) Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Lemtrada (alemtuzumab)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Limitations of Use: Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
Drug Name: Mavenclad (cladribine)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Limitations of Use: Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
Drug Name: Ocrevus (ocrelizumab), Ocrevus Zunovo (ocrelizumab)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. **Primary Progressive Forms of Multiple Sclerosis (PPMS)** Indicated for the treatment of primary progressive MS, in adults.
Drug Name: Tascenso ODT (fingolimod)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

2 . Criteria

Product Name:Brand Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone 40mg/mL, Generic glatiramer acetate, Glatopa, Kesimpta*, Mayzent, Generic Teriflunomide, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AUBAGIO	TERIFLUNOMIDE TAB 7 MG	62404070000320	Brand

AUBAGIO	TERIFLUNOMIDE TAB 14 MG	62404070000330	Brand
BETASERON	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Brand
AVONEX PEN	INTERFERON BETA-1A IM AUTO-INJECTOR KIT 30 MCG/0.5ML	6240306045F530	Brand
AVONEX	INTERFERON BETA-1A IM PREFILLED SYRINGE KIT 30 MCG/0.5ML	6240306045F830	Brand
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (12) STARTER PACK	6240707020B720	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 0.25 MG (BASE EQUIV)	62407070200320	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 2 MG (BASE EQUIV)	62407070200340	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DR STARTER BOTTLE 231 MG	62405530006520	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DELAYED RELEASE 231 MG	62405530006540	Brand
BAFIERTAM	MONOMETHYL FUMARATE CAPSULE DELAYED RELEASE 95 MG	62405550006520	Brand
KESIMPTA	OFATUMUMAB SOLN AUTO-INJECTOR 20 MG/0.4ML	6240506500D520	Brand
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (7) STARTER PACK	6240707020B710	
MAYZENT	SIPONIMOD FUMARATE TAB 1 MG (BASE EQUIV)	62407070200330	
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 7 MG	62404070000320	Generic
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 14 MG	62404070000330	Generic
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - For Brand Aubagio, trial and failure (of a minimum 4-week supply), or intolerance to generic teriflunomide

Notes	*For Kesimpta, there is a QL Override (For new starts only): Please e nter 2 PAs as follows with the same start date: First PA: Approve 3 syr inges or pens per 28 days for the first month (Loading dose has a MD D of 0.05); Second PA: Approve 1 syringe or pen per 28 days (no ove rrides needed) for 12 months. (Kesimpta is hard-coded with a quantity of 1 syringe or pen per 28 days; 0.4 mL per 20 mg pen or syringe. Ma intenance dose has a MDD of 0.02)

Product Name:Brand Copaxone 20mg/mL	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Trial and failure (of a minimum 4-week supply), or intolerance to generic glatiramer acetate

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PEN-INJECTOR 125 MCG/0.5ML	6240307530D520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK	6240307530D550	Brand
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PREFILLED SYRINGE 125 MCG/0.5ML	6240307530E520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PREF SYR 63 & 94 MCG/0.5ML PACK	6240307530E550	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 22 MCG/0.5ML (12MU/ML)	6240306045D520	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 44 MCG/0.5ML (24MU/ML)	6240306045D540	Brand
REBIF REBIDOSE TITRATION PACK	INTERFERON BETA-1A AUTO-INJ 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045D560	Brand

REBIF	INTERFERON BETA-1A SOLN PREF SYR 22 MCG/0.5ML (12MU/ML)	6240306045E520	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 44 MCG/0.5ML (24MU/ML)	6240306045E540	Brand
REBIF TITRATION PACK	INTERFERON BETA-1A PREF SYR 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045E560	Brand
EXTAVIA	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
PLEGRIDY	PEGINTERFERON BETA-1A IM SOLN PREFILLED SYR 125 MCG/0.5ML	6240307530E521	Brand
PONVORY 14-DAY STARTER PACK	PONESIMOD TAB STARTER PACK 2,3,4,5,6,7,8,9 &10 MG	6240706000B720	Brand
PONVORY	PONESIMOD TAB 20 MG	62407060000320	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 For continuation of therapy

OR

2.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Kesimpta (ofatumumab)
- Vumerity (diroximel fumarate)
- Mayzent (siponimod)

- Zeposia (ozanimod)

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Tascenso ODT	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.25 MG	62407025207220	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.5 MG	62407025207230	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - Patient is 10 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 18 years of age or older

AND

3.1.2 One of the following:

3.1.2.1 For continuation of therapy

OR

3.1.2.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Kesimpta (ofatumumab)
- Dimethyl fumarate
- Fingolimod
- Mayzent (siponimod)
- Vumerity (diroximel fumarate)
- Zeposia (ozanimod)

OR

3.2 Both of the following:

3.2.1 Patient is younger than 18 years of age

AND

3.2.2 One of the following:

3.2.2.1 Both of the following:

- Patient weighs greater than or equal to 40kg

- Trial and failure (of a minimum 4-week supply) or intolerance to generic fingolimod

OR

3.2.2.2 Both of the following:

- Patient weighs less than 40kg
- Trial and failure (of a minimum 4-week supply) or intolerance to Gilenya (fingolimod)

AND

4 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Patient is unable to take oral tablets

Product Name:Brand Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone 40mg/mL, Extavia, Generic glatiramer acetate, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Generic Teriflunomide, Vumerity

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PEN-INJECTOR 125 MCG/0.5ML	6240307530D520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK	6240307530D550	Brand
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PREFILLED SYRINGE 125 MCG/0.5ML	6240307530E520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PREF SYR 63 & 94 MCG/0.5ML PACK	6240307530E550	Brand

AUBAGIO	TERIFLUNOMIDE TAB 7 MG	62404070000320	Brand
AUBAGIO	TERIFLUNOMIDE TAB 14 MG	62404070000330	Brand
BETASERON	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 22 MCG/0.5ML (12MU/ML)	6240306045D520	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 44 MCG/0.5ML (24MU/ML)	6240306045D540	Brand
REBIF REBIDOSE TITRATION PACK	INTERFERON BETA-1A AUTO-INJ 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045D560	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 22 MCG/0.5ML (12MU/ML)	6240306045E520	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 44 MCG/0.5ML (24MU/ML)	6240306045E540	Brand
REBIF TITRATION PACK	INTERFERON BETA-1A PREF SYR 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045E560	Brand
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Brand
AVONEX PEN	INTERFERON BETA-1A IM AUTO-INJECTOR KIT 30 MCG/0.5ML	6240306045F530	Brand
AVONEX	INTERFERON BETA-1A IM PREFILLED SYRINGE KIT 30 MCG/0.5ML	6240306045F830	Brand
EXTAVIA	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (12) STARTER PACK	6240707020B720	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 0.25 MG (BASE EQUIV)	62407070200320	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 2 MG (BASE EQUIV)	62407070200340	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DR STARTER BOTTLE 231 MG	62405530006520	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DELAYED RELEASE 231 MG	62405530006540	Brand
BAFIERTAM	MONOMETHYL FUMARATE CAPSULE DELAYED RELEASE 95 MG	62405550006520	Brand
KESIMPTA	OFATUMUMAB SOLN AUTO-INJECTOR 20 MG/0.4ML	6240506500D520	Brand

PLEGRIDY	PEGINTERFERON BETA-1A IM SOLN PREFILLED SYR 125 MCG/0.5ML	6240307530E521	Brand
PONVORY 14-DAY STARTER PACK	PONESIMOD TAB STARTER PACK 2,3,4,5,6,7,8,9 &10 MG	6240706000B720	Brand
PONVORY	PONESIMOD TAB 20 MG	62407060000320	Brand
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (7) STARTER PACK	6240707020B710	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 1 MG (BASE EQUIV)	62407070200330	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.25 MG	62407025207220	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.5 MG	62407025207230	Brand
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 7 MG	62404070000320	Generic
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 14 MG	62404070000330	Generic
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - For Brand Aubagio, trial and failure (of a minimum 4-week supply), or intolerance to generic teriflunomide

Product Name:Brand Copaxone 20mg/mL	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Trial and failure (of a minimum 4-week supply), or intolerance to generic glatiramer acetate

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PEN-INJECTOR 125 MCG/0.5ML	6240307530D520	Brand

PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK	6240307530D550	Brand
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PREFILLED SYRINGE 125 MCG/0.5ML	6240307530E520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PREF SYR 63 & 94 MCG/0.5ML PACK	6240307530E550	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 22 MCG/0.5ML (12MU/ML)	6240306045D520	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 44 MCG/0.5ML (24MU/ML)	6240306045D540	Brand
REBIF REBIDOSE TITRATION PACK	INTERFERON BETA-1A AUTO-INJ 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045D560	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 22 MCG/0.5ML (12MU/ML)	6240306045E520	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 44 MCG/0.5ML (24MU/ML)	6240306045E540	Brand
REBIF TITRATION PACK	INTERFERON BETA-1A PREF SYR 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045E560	Brand
EXTAVIA	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
PLEGRIDY	PEGINTERFERON BETA-1A IM SOLN PREFILLED SYR 125 MCG/0.5ML	6240307530E521	Brand
PONVORY 14-DAY STARTER PACK	PONESIMOD TAB STARTER PACK 2,3,4,5,6,7,8,9 &10 MG	6240706000B720	Brand
PONVORY	PONESIMOD TAB 20 MG	62407060000320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

2.1.2 Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Kesimpta (ofatumumab)
- Mayzent (siponimod)
- Vumerity (diroximel fumarate)
- Zeposia (ozanimod)

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Tascenso ODT	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.25 MG	62407025207220	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.5 MG	62407025207230	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - Patient is 10 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 18 years of age or older

AND

3.1.2 One of the following:

3.1.2.1 Both of the following:

3.1.2.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

3.1.2.1.2 Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

OR

3.1.2.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Kesimpta (ofatumumab)
- Vumerity (diroximel fumarate)
- Mayzent (siponimod)
- Zeposia (ozanimod)

OR

3.2 Both of the following:

3.2.1 Patient is younger than 18 years of age

AND

3.2.2 One of the following:

3.2.2.1 All of the following:

3.2.2.1.1 Patient weighs greater than or equal to 40kg

AND

3.2.2.1.2 Submission of medical records (e.g., chart notes) confirming lack of adequate clinical response (with related symptoms) with generic fingolimod

AND

3.2.2.1.3 Submission of medical records confirming generic fingolimod has not been effective AND valid clinical justification provided explaining how the Tascenso ODT is expected to provide benefit when generic fingolimod has not been shown to be effective despite having the same active ingredient

OR

3.2.2.2 All of the following:

3.2.2.2.1 Patient weighs les than 40kg

AND

3.2.2.2.2 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to Gilenya 0.25mg (fingolimod)

AND

3.2.2.2.3 Submission of medical records confirming generic fingolimod has not been effective AND valid clinical justification provided explaining how the Tascenso ODT is expected to provide benefit when Gilenya 0.25mg (fingolimod) has not been shown to be effective despite having the same active ingredient

AND

4 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Patient is unable to take oral tablets

Product Name:Briumvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRIUMVI	UBLITUXIMAB-XIIY SOLN FOR IV INFUSION 150 MG/6ML	62405085052030	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Briumvi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRIUMVI	UBLITUXIMAB-XIIY SOLN FOR IV INFUSION 150 MG/6ML	62405085052030	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Lemtrada	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEMTRADA	ALEMTUZUMAB IV INJ 12 MG/1.2ML (10 MG/ML)	62405010002020	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with alemtuzumab

AND

2.1.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 Both of the following: [E]

2.2.1 Patient has previously received treatment with alemtuzumab

AND

2.2.2 At least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Mavenclad	
Approval Length	2 Month(s) [H]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (4 TABS)	6240101500B718	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (5 TABS)	6240101500B722	Brand

MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (6 TABS)	6240101500B726	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (7 TABS)	6240101500B732	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (8 TABS)	6240101500B736	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (9 TABS)	6240101500B740	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (10 TABS)	6240101500B744	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with cladribine

AND

2.1.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 Both of the following:

2.2.1 Patient has previously received treatment with cladribine

AND

2.2.2 Patient has not already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus, Ocrevus Zunovo	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS	OCRELIZUMAB SOLN FOR IV INFUSION 300 MG/10ML	62405060002020	Brand
OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus, Ocrevus Zunovo	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS	OCRELIZUMAB SOLN FOR IV INFUSION 300 MG/10ML	62405060002020	Brand
OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus, Ocrevus Zunovo	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS	OCRELIZUMAB SOLN FOR IV INFUSION 300 MG/10ML	62405060002020	Brand

OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus, Ocrevus Zunovo	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS	OCRELIZUMAB SOLN FOR IV INFUSION 300 MG/10ML	62405060002020	Brand

OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus Zunovo	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions)

AND

2 - One of the following:

2.1 Submission of medical records (e.g., chart notes) or paid claims confirming a trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 Both of the following:

2.2.1 Submission of medical records (e.g., chart notes) or paid claims confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

2.2.2 Patient demonstrates positive clinical response to therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta])

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus Zunovo	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. According to the National MS Society, of the four disease courses that have been identified in MS, relapsing-remitting MS (RRMS) is characterized primarily by relapses, and secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. These two constitute “relapsing forms of MS” if they describe a disease course that is characterized by the occurrence of relapses. [7] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [6]
B. Initiation of treatment with an interferon beta medication or glatiramer acetate should be considered as soon as possible following a definite diagnosis of MS with active, relapsing disease, and may also be considered for selected patients with a first attack who are at high risk of MS. [6]
C. Based on several years of experience with glatiramer acetate and interferon beta 1a and 1b, it is the consensus of researchers and clinicians with expertise in MS that these agents are likely to reduce future disease activity and improve quality of life for many individuals with relapsing forms of MS, including those with secondary progressive disease who continue to have relapses. For those who are appropriate candidates for one of these drugs, treatment must be sustained for years. Cessation of treatment may result in a resumption of pre-treatment disease activity. [6]
D. MS specialists will use Copaxone in relapsing forms of disease, including SPMS with relapses. While there have been no trials of Copaxone in SPMS (so we have no evidenced-based data upon which to make decisions or recommendations), it's clear that where there are relapses, the injectable therapies are partially effective – they reduce relapses and new lesions on MRI. In SPMS, the trials suggest that the interferons work better in earlier, more inflammatory (i.e. those with relapses prior to the trial and with gadolinium-enhancing lesions, which is the MRI equivalent of active inflammation). Since Copaxone and the interferons appear to have rather similar efficacy in the head-to-head trials, most assume that Copaxone has a similar efficacy in SPMS: where there are relapses or active inflammation on MRI, it will likely have some benefit. Thus, most MS specialists will use Copaxone in patients with SPMS who have persistent relapses. [8]
E. According to Prescribing Information, the recommended dosage of Lemtrada is 12 mg/day administered by intravenous infusion for 2 treatment courses (first treatment

course: 12 mg/day on 5 consecutive days; second treatment course: 12 mg/day on 3 consecutive days administered 12 months after the first treatment course). Following the second treatment course, subsequent treatment courses of 12 mg per day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment courses. [11]

F. Not to exceed the FDA-recommended dosage of 2 treatment courses (with the second course administered 43 weeks following the last dose of the first course). According to Prescribing Information, the recommended cumulative dosage of Mavenclad is 3.5 mg per kg body weight administered orally and divided into 2 yearly treatment courses (1.75 mg per kg per treatment course). Each treatment course is divided into 2 treatment cycles with the second cycle of each course administered 23 to 27 days after the last dose of the first cycle. Following the administration of 2 treatment courses, do not administer additional Mavenclad treatment during the next 2 years. Treatment during these 2 years may further increase the risk of malignancy. The safety and efficacy of reinitiating Mavenclad more than 2 years after completing 2 treatment courses has not been studied. [16]
G. The advantage of using combination disease-modifying therapy (DMT) compared to monotherapy DMT use has not been demonstrated, but there are safety concerns, such as reduced efficacy or disease aggravation, with combination use. [22, 23]
H. Due to the unique dosing regimen of Mavenclad, a two-month PA approval length is implemented to ensure medication for the second cycle of the same treatment course is accessible to patients before the auth expires. [16]

4 . References

1. Avonex Prescribing Information. Biogen Inc. Cambridge, MA. July 2023.
2. Betaseron Prescribing Information. Bayer. Whippany, NJ. July 2023.
3. Copaxone Prescribing Information. Teva Pharmaceuticals. North Wales, PA. November 2023.
4. Extavia Prescribing Information. Novartis. East Hanover, NJ. July 2023.
5. Rebif Prescribing Information. Serono Inc. Rockland, MA. July 2023..
6. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.
7. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed April 5, 2024
8. Per clinical consultation with MS specialist, December 29, 2010.
9. Plegridy Prescribing Information. Biogen Idec Inc. Cambridge, MA. July 2023.
10. Aubagio Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2023.
11. Lemtrada Prescribing Information. Genzyme Corporation. Cambridge, MA. February 2024.
12. Glatopa Prescribing Information. Sandoz Inc. Princeton, NJ. November 2023.
13. Hawker K, O'Connor P, Freedman MS, et al. Rituximab in patients with primary progressive multiple sclerosis: results of a randomized double-blind placebo-controlled multicenter trial. Ann Neurol. 2009; Oct;66(4):460-71.
14. Ocrevus Prescribing Information. Genentech, Inc. San Francisco, CA. September 2024.
15. Mayzent Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2024.

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17. Vumerity Prescribing Information. Biogen Inc. Cambridge, MA. December 2023.
18. Bafiertam Prescribing Information. Banner Life Sciences. High Point, NC. December 2023.
19. Kesimpta Prescribing Information. Novartis Pharmaceuticals Corporation. East NJ. April 2024.
20. Hauser S, Bar-Or A, Cohen J et al. Ofatumumab versus Teriflunomide in Multiple Sclerosis. New England Journal of Medicine. 2020;383(6):546-557.
21. Ponvory Prescribing Information. Janssen Pharmaceuticals Inc. Titusville, NJ. August 2023.
22. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. Mayo Clinic Proceedings, 89(2), 225-240.
23. Sorensen, P., Lycke, J., Erälinna, J., Edland, A., Wu, X., & Frederiksen, J. et al. (2011). Simvastatin as add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (SIMCOMBIN study): a placebo-controlled randomised phase 4 trial. The Lancet Neurology, 10(8), 691-701.
24. Tascenso ODT Prescribing Information. Cycle Pharmaceuticals Ltd. Cambridge, United Kingdom. December 2022.
25. Briumvi Prescribing Information. TG Therapeutics, Inc. Morrisville, NC. December 2022.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-233270
Guideline Name	Multiple Sclerosis (MS) Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/20/2000
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Aubagio (teriflunomide), Avonex (interferon beta-1a), Bafiertam (monomethyl fumarate), Betaseron (interferon beta-1b), Briumvi (ublituximab-xiiy), Copaxone (glatiramer acetate), Extavia (interferon beta-1b), Glatopa (glatiramer acetate)
Relapsing forms of multiple sclerosis (MS) Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Kesimpta (ofatumumab), Mayzent (siponimod), Plegridy (peginterferon beta-1a), Ponvory (ponesimod), Rebif (interferon beta-1a), Vumerity (diroximel fumarate)
Relapsing forms of multiple sclerosis (MS) Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Lemtrada (alemtuzumab)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Limitations of Use: Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
Drug Name: Mavenclad (cladribine)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Limitations of Use: Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
Drug Name: Ocrevus (ocrelizumab), Ocrevus Zunovo (ocrelizumab)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. **Primary Progressive Forms of Multiple Sclerosis (PPMS)** Indicated for the treatment of primary progressive MS, in adults.
Drug Name: Tascenso ODT (fingolimod)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

2 . Criteria

Product Name:Brand Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone 40mg/mL, Generic glatiramer acetate, Glatopa, Kesimpta*, Mayzent, Generic Teriflunomide, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AUBAGIO	TERIFLUNOMIDE TAB 7 MG	62404070000320	Brand

AUBAGIO	TERIFLUNOMIDE TAB 14 MG	62404070000330	Brand
BETASERON	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Brand
AVONEX PEN	INTERFERON BETA-1A IM AUTO-INJECTOR KIT 30 MCG/0.5ML	6240306045F530	Brand
AVONEX	INTERFERON BETA-1A IM PREFILLED SYRINGE KIT 30 MCG/0.5ML	6240306045F830	Brand
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (12) STARTER PACK	6240707020B720	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 0.25 MG (BASE EQUIV)	62407070200320	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 2 MG (BASE EQUIV)	62407070200340	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DR STARTER BOTTLE 231 MG	62405530006520	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DELAYED RELEASE 231 MG	62405530006540	Brand
BAFIERTAM	MONOMETHYL FUMARATE CAPSULE DELAYED RELEASE 95 MG	62405550006520	Brand
KESIMPTA	OFATUMUMAB SOLN AUTO-INJECTOR 20 MG/0.4ML	6240506500D520	Brand
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (7) STARTER PACK	6240707020B710	
MAYZENT	SIPONIMOD FUMARATE TAB 1 MG (BASE EQUIV)	62407070200330	
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 7 MG	62404070000320	Generic
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 14 MG	62404070000330	Generic
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - For Brand Aubagio, trial and failure (of a minimum 4-week supply), or intolerance to generic teriflunomide

Notes	*For Kesimpta, there is a QL Override (For new starts only): Please e nter 2 PAs as follows with the same start date: First PA: Approve 3 syr inges or pens per 28 days for the first month (Loading dose has a MD D of 0.05); Second PA: Approve 1 syringe or pen per 28 days (no ove rrides needed) for 12 months. (Kesimpta is hard-coded with a quantity of 1 syringe or pen per 28 days; 0.4 mL per 20 mg pen or syringe. Ma intenance dose has a MDD of 0.02)

Product Name:Brand Copaxone 20mg/mL	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Trial and failure (of a minimum 4-week supply), or intolerance to generic glatiramer acetate

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PEN-INJECTOR 125 MCG/0.5ML	6240307530D520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK	6240307530D550	Brand
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PREFILLED SYRINGE 125 MCG/0.5ML	6240307530E520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PREF SYR 63 & 94 MCG/0.5ML PACK	6240307530E550	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 22 MCG/0.5ML (12MU/ML)	6240306045D520	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 44 MCG/0.5ML (24MU/ML)	6240306045D540	Brand
REBIF REBIDOSE TITRATION PACK	INTERFERON BETA-1A AUTO-INJ 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045D560	Brand

REBIF	INTERFERON BETA-1A SOLN PREF SYR 22 MCG/0.5ML (12MU/ML)	6240306045E520	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 44 MCG/0.5ML (24MU/ML)	6240306045E540	Brand
REBIF TITRATION PACK	INTERFERON BETA-1A PREF SYR 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045E560	Brand
EXTAVIA	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
PLEGRIDY	PEGINTERFERON BETA-1A IM SOLN PREFILLED SYR 125 MCG/0.5ML	6240307530E521	Brand
PONVORY 14-DAY STARTER PACK	PONESIMOD TAB STARTER PACK 2,3,4,5,6,7,8,9 &10 MG	6240706000B720	Brand
PONVORY	PONESIMOD TAB 20 MG	62407060000320	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 For continuation of therapy

OR

2.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Kesimpta (ofatumumab)
- Vumerity (diroximel fumarate)
- Mayzent (siponimod)

- Zeposia (ozanimod)

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Tascenso ODT	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.25 MG	62407025207220	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.5 MG	62407025207230	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - Patient is 10 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 18 years of age or older

AND

3.1.2 One of the following:

3.1.2.1 For continuation of therapy

OR

3.1.2.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Kesimpta (ofatumumab)
- Dimethyl fumarate
- Fingolimod
- Mayzent (siponimod)
- Vumerity (diroximel fumarate)
- Zeposia (ozanimod)

OR

3.2 Both of the following:

3.2.1 Patient is younger than 18 years of age

AND

3.2.2 One of the following:

3.2.2.1 Both of the following:

- Patient weighs greater than or equal to 40kg

- Trial and failure (of a minimum 4-week supply) or intolerance to generic fingolimod

OR

3.2.2.2 Both of the following:

- Patient weighs less than 40kg
- Trial and failure (of a minimum 4-week supply) or intolerance to Gilenya (fingolimod)

AND

4 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Patient is unable to take oral tablets

Product Name:Brand Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone 40mg/mL, Extavia, Generic glatiramer acetate, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Generic Teriflunomide, Vumerity

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PEN-INJECTOR 125 MCG/0.5ML	6240307530D520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK	6240307530D550	Brand
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PREFILLED SYRINGE 125 MCG/0.5ML	6240307530E520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PREF SYR 63 & 94 MCG/0.5ML PACK	6240307530E550	Brand

AUBAGIO	TERIFLUNOMIDE TAB 7 MG	62404070000320	Brand
AUBAGIO	TERIFLUNOMIDE TAB 14 MG	62404070000330	Brand
BETASERON	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 22 MCG/0.5ML (12MU/ML)	6240306045D520	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 44 MCG/0.5ML (24MU/ML)	6240306045D540	Brand
REBIF REBIDOSE TITRATION PACK	INTERFERON BETA-1A AUTO-INJ 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045D560	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 22 MCG/0.5ML (12MU/ML)	6240306045E520	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 44 MCG/0.5ML (24MU/ML)	6240306045E540	Brand
REBIF TITRATION PACK	INTERFERON BETA-1A PREF SYR 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045E560	Brand
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Brand
AVONEX PEN	INTERFERON BETA-1A IM AUTO-INJECTOR KIT 30 MCG/0.5ML	6240306045F530	Brand
AVONEX	INTERFERON BETA-1A IM PREFILLED SYRINGE KIT 30 MCG/0.5ML	6240306045F830	Brand
EXTAVIA	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (12) STARTER PACK	6240707020B720	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 0.25 MG (BASE EQUIV)	62407070200320	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 2 MG (BASE EQUIV)	62407070200340	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DR STARTER BOTTLE 231 MG	62405530006520	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DELAYED RELEASE 231 MG	62405530006540	Brand
BAFIERTAM	MONOMETHYL FUMARATE CAPSULE DELAYED RELEASE 95 MG	62405550006520	Brand
KESIMPTA	OFATUMUMAB SOLN AUTO-INJECTOR 20 MG/0.4ML	6240506500D520	Brand

PLEGRIDY	PEGINTERFERON BETA-1A IM SOLN PREFILLED SYR 125 MCG/0.5ML	6240307530E521	Brand
PONVORY 14-DAY STARTER PACK	PONESIMOD TAB STARTER PACK 2,3,4,5,6,7,8,9 &10 MG	6240706000B720	Brand
PONVORY	PONESIMOD TAB 20 MG	62407060000320	Brand
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (7) STARTER PACK	6240707020B710	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 1 MG (BASE EQUIV)	62407070200330	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.25 MG	62407025207220	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.5 MG	62407025207230	Brand
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 7 MG	62404070000320	Generic
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 14 MG	62404070000330	Generic
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - For Brand Aubagio, trial and failure (of a minimum 4-week supply), or intolerance to generic teriflunomide

Product Name:Brand Copaxone 20mg/mL	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Trial and failure (of a minimum 4-week supply), or intolerance to generic glatiramer acetate

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PEN-INJECTOR 125 MCG/0.5ML	6240307530D520	Brand

PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK	6240307530D550	Brand
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PREFILLED SYRINGE 125 MCG/0.5ML	6240307530E520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PREF SYR 63 & 94 MCG/0.5ML PACK	6240307530E550	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 22 MCG/0.5ML (12MU/ML)	6240306045D520	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 44 MCG/0.5ML (24MU/ML)	6240306045D540	Brand
REBIF REBIDOSE TITRATION PACK	INTERFERON BETA-1A AUTO-INJ 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045D560	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 22 MCG/0.5ML (12MU/ML)	6240306045E520	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 44 MCG/0.5ML (24MU/ML)	6240306045E540	Brand
REBIF TITRATION PACK	INTERFERON BETA-1A PREF SYR 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045E560	Brand
EXTAVIA	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
PLEGRIDY	PEGINTERFERON BETA-1A IM SOLN PREFILLED SYR 125 MCG/0.5ML	6240307530E521	Brand
PONVORY 14-DAY STARTER PACK	PONESIMOD TAB STARTER PACK 2,3,4,5,6,7,8,9 &10 MG	6240706000B720	Brand
PONVORY	PONESIMOD TAB 20 MG	62407060000320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

2.1.2 Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Kesimpta (ofatumumab)
- Mayzent (siponimod)
- Vumerity (diroximel fumarate)
- Zeposia (ozanimod)

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Tascenso ODT	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.25 MG	62407025207220	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.5 MG	62407025207230	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - Patient is 10 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 18 years of age or older

AND

3.1.2 One of the following:

3.1.2.1 Both of the following:

3.1.2.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

3.1.2.1.2 Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

OR

3.1.2.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Kesimpta (ofatumumab)
- Vumerity (diroximel fumarate)
- Mayzent (siponimod)
- Zeposia (ozanimod)

OR

3.2 Both of the following:

3.2.1 Patient is younger than 18 years of age

AND

3.2.2 One of the following:

3.2.2.1 All of the following:

3.2.2.1.1 Patient weighs greater than or equal to 40kg

AND

3.2.2.1.2 Submission of medical records (e.g., chart notes) confirming lack of adequate clinical response (with related symptoms) with generic fingolimod

AND

3.2.2.1.3 Submission of medical records confirming generic fingolimod has not been effective AND valid clinical justification provided explaining how the Tascenso ODT is expected to provide benefit when generic fingolimod has not been shown to be effective despite having the same active ingredient

OR

3.2.2.2 All of the following:

3.2.2.2.1 Patient weighs les than 40kg

AND

3.2.2.2.2 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to Gilenya 0.25mg (fingolimod)

AND

3.2.2.2.3 Submission of medical records confirming generic fingolimod has not been effective AND valid clinical justification provided explaining how the Tascenso ODT is expected to provide benefit when Gilenya 0.25mg (fingolimod) has not been shown to be effective despite having the same active ingredient

AND

4 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Patient is unable to take oral tablets

Product Name:Briumvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRIUMVI	UBLITUXIMAB-XIIY SOLN FOR IV INFUSION 150 MG/6ML	62405085052030	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Briumvi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BRIUMVI	UBLITUXIMAB-XIIY SOLN FOR IV INFUSION 150 MG/6ML	62405085052030	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Lemtrada	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEMTRADA	ALEMTUZUMAB IV INJ 12 MG/1.2ML (10 MG/ML)	62405010002020	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with alemtuzumab

AND

2.1.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 Both of the following: [E]

2.2.1 Patient has previously received treatment with alemtuzumab

AND

2.2.2 At least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Mavenclad	
Approval Length	2 Month(s) [H]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (4 TABS)	6240101500B718	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (5 TABS)	6240101500B722	Brand

MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (6 TABS)	6240101500B726	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (7 TABS)	6240101500B732	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (8 TABS)	6240101500B736	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (9 TABS)	6240101500B740	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (10 TABS)	6240101500B744	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with cladribine

AND

2.1.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 Both of the following:

2.2.1 Patient has previously received treatment with cladribine

AND

2.2.2 Patient has not already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus, Ocrevus Zunovo	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS	OCRELIZUMAB SOLN FOR IV INFUSION 300 MG/10ML	62405060002020	Brand
OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus, Ocrevus Zunovo	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS	OCRELIZUMAB SOLN FOR IV INFUSION 300 MG/10ML	62405060002020	Brand
OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus, Ocrevus Zunovo	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS	OCRELIZUMAB SOLN FOR IV INFUSION 300 MG/10ML	62405060002020	Brand

OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus, Ocrevus Zunovo	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS	OCRELIZUMAB SOLN FOR IV INFUSION 300 MG/10ML	62405060002020	Brand

OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus Zunovo	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions)

AND

2 - One of the following:

2.1 Submission of medical records (e.g., chart notes) or paid claims confirming a trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 Both of the following:

2.2.1 Submission of medical records (e.g., chart notes) or paid claims confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

2.2.2 Patient demonstrates positive clinical response to therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta])

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus Zunovo	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS ZUNOVO	OCRELIZUMAB-HYALURONIDASE-OCSQ INJ 920-23000 MG-UNIT/23ML	62409902602040	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. According to the National MS Society, of the four disease courses that have been identified in MS, relapsing-remitting MS (RRMS) is characterized primarily by relapses, and secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. These two constitute “relapsing forms of MS” if they describe a disease course that is characterized by the occurrence of relapses. [7] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [6]
B. Initiation of treatment with an interferon beta medication or glatiramer acetate should be considered as soon as possible following a definite diagnosis of MS with active, relapsing disease, and may also be considered for selected patients with a first attack who are at high risk of MS. [6]
C. Based on several years of experience with glatiramer acetate and interferon beta 1a and 1b, it is the consensus of researchers and clinicians with expertise in MS that these agents are likely to reduce future disease activity and improve quality of life for many individuals with relapsing forms of MS, including those with secondary progressive disease who continue to have relapses. For those who are appropriate candidates for one of these drugs, treatment must be sustained for years. Cessation of treatment may result in a resumption of pre-treatment disease activity. [6]
D. MS specialists will use Copaxone in relapsing forms of disease, including SPMS with relapses. While there have been no trials of Copaxone in SPMS (so we have no evidenced-based data upon which to make decisions or recommendations), it's clear that where there are relapses, the injectable therapies are partially effective – they reduce relapses and new lesions on MRI. In SPMS, the trials suggest that the interferons work better in earlier, more inflammatory (i.e. those with relapses prior to the trial and with gadolinium-enhancing lesions, which is the MRI equivalent of active inflammation). Since Copaxone and the interferons appear to have rather similar efficacy in the head-to-head trials, most assume that Copaxone has a similar efficacy in SPMS: where there are relapses or active inflammation on MRI, it will likely have some benefit. Thus, most MS specialists will use Copaxone in patients with SPMS who have persistent relapses. [8]
E. According to Prescribing Information, the recommended dosage of Lemtrada is 12 mg/day administered by intravenous infusion for 2 treatment courses (first treatment

course: 12 mg/day on 5 consecutive days; second treatment course: 12 mg/day on 3 consecutive days administered 12 months after the first treatment course). Following the second treatment course, subsequent treatment courses of 12 mg per day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment courses. [11]

F. Not to exceed the FDA-recommended dosage of 2 treatment courses (with the second course administered 43 weeks following the last dose of the first course). According to Prescribing Information, the recommended cumulative dosage of Mavenclad is 3.5 mg per kg body weight administered orally and divided into 2 yearly treatment courses (1.75 mg per kg per treatment course). Each treatment course is divided into 2 treatment cycles with the second cycle of each course administered 23 to 27 days after the last dose of the first cycle. Following the administration of 2 treatment courses, do not administer additional Mavenclad treatment during the next 2 years. Treatment during these 2 years may further increase the risk of malignancy. The safety and efficacy of reinitiating Mavenclad more than 2 years after completing 2 treatment courses has not been studied. [16]
G. The advantage of using combination disease-modifying therapy (DMT) compared to monotherapy DMT use has not been demonstrated, but there are safety concerns, such as reduced efficacy or disease aggravation, with combination use. [22, 23]
H. Due to the unique dosing regimen of Mavenclad, a two-month PA approval length is implemented to ensure medication for the second cycle of the same treatment course is accessible to patients before the auth expires. [16]

4 . References

1. Avonex Prescribing Information. Biogen Inc. Cambridge, MA. July 2023.
2. Betaseron Prescribing Information. Bayer. Whippany, NJ. July 2023.
3. Copaxone Prescribing Information. Teva Pharmaceuticals. North Wales, PA. November 2023.
4. Extavia Prescribing Information. Novartis. East Hanover, NJ. July 2023.
5. Rebif Prescribing Information. Serono Inc. Rockland, MA. July 2023..
6. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.
7. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed April 5, 2024
8. Per clinical consultation with MS specialist, December 29, 2010.
9. Plegridy Prescribing Information. Biogen Idec Inc. Cambridge, MA. July 2023.
10. Aubagio Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2023.
11. Lemtrada Prescribing Information. Genzyme Corporation. Cambridge, MA. February 2024.
12. Glatopa Prescribing Information. Sandoz Inc. Princeton, NJ. November 2023.
13. Hawker K, O'Connor P, Freedman MS, et al. Rituximab in patients with primary progressive multiple sclerosis: results of a randomized double-blind placebo-controlled multicenter trial. Ann Neurol. 2009; Oct;66(4):460-71.
14. Ocrevus Prescribing Information. Genentech, Inc. San Francisco, CA. September 2024.
15. Mayzent Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2024.

16. Mavenclad Prescribing Information. EMD Serono, Inc. Rockland, MA. February 2024.
17. Vumerity Prescribing Information. Biogen Inc. Cambridge, MA. December 2023.
18. Bafiertam Prescribing Information. Banner Life Sciences. High Point, NC. December 2023.
19. Kesimpta Prescribing Information. Novartis Pharmaceuticals Corporation. East NJ. April 2024.
20. Hauser S, Bar-Or A, Cohen J et al. Ofatumumab versus Teriflunomide in Multiple Sclerosis. New England Journal of Medicine. 2020;383(6):546-557.
21. Ponvory Prescribing Information. Janssen Pharmaceuticals Inc. Titusville, NJ. August 2023.
22. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. Mayo Clinic Proceedings, 89(2), 225-240.
23. Sorensen, P., Lycke, J., Erälinna, J., Edland, A., Wu, X., & Frederiksen, J. et al. (2011). Simvastatin as add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (SIMCOMBIN study): a placebo-controlled randomised phase 4 trial. The Lancet Neurology, 10(8), 691-701.
24. Tascenso ODT Prescribing Information. Cycle Pharmaceuticals Ltd. Cambridge, United Kingdom. December 2022.
25. Briumvi Prescribing Information. TG Therapeutics, Inc. Morrisville, NC. December 2022.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228912
Guideline Name	Myalept (metreleptin for injection)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Myalept (metreleptin for injection)
Congenital or acquired generalized lipodystrophy Indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy

2 . Criteria

Product Name:Myalept	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MYALEPT	METRELEPTIN FOR SUBCUTANEOUS INJ 11.3 MG	30906050002120	Brand

Approval Criteria

1 - Diagnosis of congenital or acquired generalized lipodystrophy

AND

2 - Patient is refractory to current standards of care for lipid and diabetic management

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Documentation demonstrates that patient has at least one of the following metabolic abnormalities: [2]

- Insulin resistance (defined as requiring more than 200 units per day)
- Hypertriglyceridemia
- Diabetes mellitus

Product Name:Myalept	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MYALEPT	METRELEPTIN FOR SUBCUTANEOUS INJ 11.3 MG	30906050002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy, such as one of the following:

- Sustained reduction in hemoglobin A1c level from baseline
- Sustained reduction in triglyceride levels from baseline

3 . References

1. Myalept Prescribing Information. Amryt Pharmaceuticals DAC. Dublin, Ireland. March 2023.
2. Handelsman Y, Oral EA, Bloomgarden ZT, et al. The clinical approach to the detection of lipodystrophy – an AACE consensus statement. Endocrine Practice 2013;19(1):107-116.
3. Araujo-Vilar, D., Santini, F. Diagnosis and Treatment of Lipodystrophy: A Step-by-Step Approach. Journal of Endocrinological Investigation volume 42, pages61–73 (2019). Available at https://link.springer.com/article/10.1007/s40618-018-0887-z. Accessed July 13, 2022.
4. UptoDate: Lipodystrophic syndromes. available at: https://www.uptodate.com/contents/lipodystrophic-syndromes?search=lipodustrophy&source=search_result&selectedTitle=1%7E61&usage_type=default&display_rank=1#H28. Accessed June 24, 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228688
Guideline Name	Myobloc (rimabotulinumtoxin B)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Myobloc (rimabotulinumtoxin B)
Cervical Dystonia (CD) Indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. **Chronic Sialorrhea** Indicated for the treatment of chronic sialorrhea in adults.

2 . Criteria

Product Name:Myobloc	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MYOBLOC	RIMABOTULINUMTOXINB INJ 2500 UNIT/0.5ML	74400020102018	Brand
MYOBLOC	RIMABOTULINUMTOXINB INJ 5000 UNIT/ML	74400020102020	Brand
MYOBLOC	RIMABOTULINUMTOXINB INJ 10000 UNIT/2ML	74400020102022	Brand

Approval Criteria

1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis) [2]

Product Name:Myobloc	
Diagnosis	Chronic Sialorrhea
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MYOBLOC	RIMABOTULINUMTOXINB INJ 2500 UNIT/0.5ML	74400020102018	Brand
MYOBLOC	RIMABOTULINUMTOXINB INJ 5000 UNIT/ML	74400020102020	Brand
MYOBLOC	RIMABOTULINUMTOXINB INJ 10000 UNIT/2ML	74400020102022	Brand

Approval Criteria

1 - Diagnosis of chronic sialorrhea

Product Name:Myobloc	
Diagnosis	All indications listed above
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MYOBLOC	RIMABOTULINUMTOXINB INJ 2500 UNIT/0.5ML	74400020102018	Brand
MYOBLOC	RIMABOTULINUMTOXINB INJ 5000 UNIT/ML	74400020102020	Brand
MYOBLOC	RIMABOTULINUMTOXINB INJ 10000 UNIT/2ML	74400020102022	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

AND

2 - At least 3 months have elapsed since the last treatment [B]

3 . Endnotes

A. The duration of effect in patients responding to Myobloc treatment has been observed in studies to be between 12 and 16 weeks at doses of 5,000 Units or 10,000 Units. [1]
B. The typical duration of effect of each treatment is up to 3 months with the repeat of treatments should be determined by clinical response but should generally be no frequent than every 12 weeks.

4 . References

1. Myobloc Prescribing Information. Solstice Neurosciences, LLC. Louisville, KY. March 2021.
2. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May;86(19):1818-26.

Naglazyme (galsulfase injection)

Prior Authorization Guideline

Guideline ID	GL-228689
Guideline Name	Naglazyme (galsulfase injection)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Naglazyme (galsulfase injection)
Mucopolysaccharidosis (MPS VI) Indicated for patients with Mucopolysaccharidosis VI (MPS VI). Naglazyme has been shown to improve walking and stair-climbing capacity.

2 . Criteria

Product Name:Naglazyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NAGLAZYME	GALSULFASE SOLN FOR IV INFUSION 1 MG/ML	30907535002020	Brand

Approval Criteria

1 - Diagnosis of Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy Syndrome)

Product Name:Naglazyme	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NAGLAZYME	GALSULFASE SOLN FOR IV INFUSION 1 MG/ML	30907535002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Naglazyme Prescribing Information. BioMarin Pharmaceuticals Inc. April 2020.

Prior Authorization Guideline

Guideline ID	GL-228691
Guideline Name	Nascobal (cyanocobalamin) Spray- Non Formulary
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nascobal (cyanocobalamin) Spray
Pernicious Anemia Indicated for the maintenance of normal hematologic status in pernicious anemia patients who are in remission following intramuscular vitamin B12 therapy and who have no nervous system involvement. **Vitamin B12 Deficiencies** Indicated as a supplement for other vitamin B12 deficiencies, including:1)Dietary deficiency of vitamin B12 occurring in strict vegetarians (Isolated vitamin B12 deficiency is very rare). 2) Malabsorption of vitamin B12 resulting from structural or functional damage to the stomach, where intrinsic factor is secreted, or to the ileum, where intrinsic factor facilitates vitamin B12 absorption. These conditions include HIV infection, AIDS, Crohn's disease, tropical sprue, and nontropical sprue (idiopathic steatorrhea, gluten-induced enteropathy). Folate deficiency in these patients is usually more severe than vitamin B12 deficiency. 3)Inadequate secretion of intrinsic factor, resulting from lesions that destroy the gastric mucosa (ingestion of corrosives, extensive neoplasia), and a number of conditions associated with a variable degree of gastric atrophy (such as multiple sclerosis, HIV infection, AIDS, certain endocrine disorders, iron deficiency, and subtotal gastrectomy). Total gastrectomy always produces vitamin B12 deficiency. Structural lesions leading to vitamin B12 deficiency include regional ileitis, ileal resections, malignancies, etc. 4)Competition for vitamin B12 by intestinal parasites or bacteria. The fish tapeworm (Diphyllobothrium latum)

absorbs huge quantities of vitamin B12 and infested patients often have associated gastric atrophy. The blind loop syndrome may produce deficiency of vitamin B12 or folate.
5)Inadequate utilization of vitamin B12. This may occur if antimetabolites for the vitamin are employed in the treatment of neoplasia

2 . Criteria

Product Name:Nascobal	
Diagnosis	Vitamin B12 Deficiency
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NASCOBAL	CYANOCOBALAMIN NASAL SPRAY 500 MCG/0.1ML	82100010002020	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting that the patient is unable to absorb vitamin B12 via the oral route due to ONE of the following:

- strict vegetarian diet
- malabsorption from structural or functional damage to the stomach or ileum
- inadequate secretion of intrinsic factor
- competition of vitamin B12 by intestinal parasites or bacteria (e.g., tapeworm, blind loop syndrome)
- inadequate utilization of vitamin B12 (e.g., antimetabolites are employed in treatment of neoplasia)

AND

2 - Patient has a documented diagnosis of trypanophobia (ie., needle-phobia)

Product Name:Nascobal	
Diagnosis	Pernicious Anemia

Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NASCOBAL	CYANOCOBALAMIN NASAL SPRAY 500 MCG/0.1ML	82100010002020	Brand

Approval Criteria

1 - Diagnosis of pernicious anemia

AND

2 - Submission of medical records (e.g., chart notes) that the patient has had a previous administration of intramuscular vitamin B-12 therapy

AND

3 - Justification provided for why the patient can no longer receive intramuscular vitamin B-12 therapy

Prior Authorization Guideline

Guideline ID	GL-233303
Guideline Name	Nemluvio (nemolizumab-ilto)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/16/2024
P&T Revision Date:	

1 . Indications

Drug Name: Nemluvio (nemolizumab-ilto)
Prurigo Nodularis (PN) Indicated for the treatment of adults with prurigo nodularis.

2 . Criteria

Product Name:Nemluvio	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEMLUVIO	NEMOLIZUMAB-ILTO FOR SUBCUTANEOUS AUTO-INJECTOR 30 MG	9079355510D420	Brand

Approval Criteria

1 - Diagnosis of prurigo nodularis (PN)

AND

2 - Patient has at least 20 nodular lesions

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Dermatologist

AND

4 - Trial and failure, contraindication, or intolerance to one medium or higher potency topical corticosteroid [2, 3]

AND

5 - Trial and failure, contraindication, or intolerance to Dupixent (dupilumab)

Product Name:Nemluvio	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEMLUVIO	NEMOLIZUMAB-ILTO FOR SUBCUTANEOUS AUTO-INJECTOR 30 MG	9079355510D420	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in the number of nodular lesions from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Nemluvio	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEMLUVIO	NEMOLIZUMAB-ILTO FOR SUBCUTANEOUS AUTO-INJECTOR 30 MG	9079355510D420	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of prurigo nodularis (PN)

AND

2 - Patient has at least 20 nodular lesions

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Dermatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one medium or higher potency topical corticosteroid [2, 3]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Dupixent (dupilumab)

3 . Background

Benefit/Coverage/Program Information

Table 1: Relative potencies of topical corticosteroids [4]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05

	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
	Dexamethasone	Cream	0.1

Lowest potency	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . References

1. Nemluvio Prescribing Information. Galderma Laboratories, L.P. Dallas, TX. August 2024.
2. Williams KA, Huang AH, Belzberg M, et al. Prurigo nodularis: pathogenesis and management. J Am Acad Dermatol. 2020;83(6):1567-75.
3. Leis M, Fleming P, Lynde CW. Prurigo nodularis: review and emerging treatments. Skin Therapy Lett. 2021;26(3):5-8.
4. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Nerlynx (neratinib)

Prior Authorization Guideline

Guideline ID	GL-233208
Guideline Name	Nerlynx (neratinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	9/27/2017
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Nerlynx (neratinib)
Early Stage Breast Cancer Indicated as a single agent for the extended adjuvant treatment of adult patients with early-stage human epidermal growth factor receptor 2 (HER2)-positive breast cancer, to follow adjuvant trastuzumab based therapy **Advanced or Metastatic Breast Cancer** Indicated for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting in combination with capecitabine.

2 . Criteria

Product Name:Nerlynx	
Diagnosis	Early Stage Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NERLYNX	NERATINIB MALEATE TAB 40 MG (BASE EQUIVALENT)	21533035100320	Brand

Approval Criteria

1 - Diagnosis of early stage breast cancer

AND

2 - Treatment duration of Nerlynx has not exceeded a total of 12 months [1, 2, 3, A]

Product Name:Nerlynx	
Diagnosis	Advanced or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NERLYNX	NERATINIB MALEATE TAB 40 MG (BASE EQUIVALENT)	21533035100320	Brand

Approval Criteria

1 - Diagnosis of advanced or metastatic breast cancer

Product Name:Nerlynx	
Diagnosis	Advanced or Metastatic Breast Cancer

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NERLYNX	NERATINIB MALEATE TAB 40 MG (BASE EQUIVALENT)	21533035100320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Per the ExteNET Lancet study, Nerlynx was administered for no more than 12 months and showed improvement in disease-free survival in trastuzumab (Herceptin)-treated patients with early breast cancer. [2]

4 . References

1. Nerlynx Prescribing Information. Puma Biotechnology, Inc. Los Angeles, CA. March 2022.
2. Chan A, Delaloge S, Holmes FA, et al. Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Oncol 2016; 17: 367-77.
3. Per Clinical Consultation with an Oncologist, August 24th, 2017.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer v.7.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 20, 2024.
5. Saura C, Garcia-Saenz JA, Xu B,et al. Safety and efficacy of neratinib in combination with capecitabine in patients with metastatic human epidermal growth factor receptor 2-positive breast cancer. J Clin Oncol. 2014 Nov 10;32(32):3626-33. doi: 10.1200/JCO.2014.56.3809.
6. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on September 20, 2024.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228477
Guideline Name	Neurologic Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Savella (milnacipran)
Fibromyalgia Indicated for the management of fibromyalgia. Savella is not approved for use in pediatric patients.
Drug Name: Lyrica CR (pregabalin extended-release)
Neuropathic pain associated with diabetic peripheral neuropathy Indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy. Efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures. **Postherpetic neuralgia** Indicated for the management of postherpetic neuralgia. Efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures.
Drug Name: Gralise (gabapentin)

Postherpetic Neuralgia (PHN) Indicated for the management of PHN. Gralise is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration.

2 . Criteria

Product Name:Savella, Brand Lyrica CR, generic pregabalin extended-release	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
SAVELLA	MILNACIPRAN HCL TAB 12.5 MG	62504050100320	Brand
SAVELLA	MILNACIPRAN HCL TAB 25 MG	62504050100330	Brand
SAVELLA	MILNACIPRAN HCL TAB 50 MG	62504050100340	Brand
SAVELLA	MILNACIPRAN HCL TAB 100 MG	62504050100350	Brand
SAVELLA TITRATION PACK	MILNACIPRAN HCL TAB 12.5 MG (5) & 25 MG (8) & 50 MG (42) PAK	62504050106320	Brand
LYRICA CR	PREGABALIN TAB ER 24HR 82.5 MG	62540060007520	Brand
LYRICA CR	PREGABALIN TAB ER 24HR 165 MG	62540060007530	Brand
LYRICA CR	PREGABALIN TAB ER 24HR 330 MG	62540060007540	Brand
PREGABALIN ER	PREGABALIN TAB ER 24HR 82.5 MG	62540060007520	Generic
PREGABALIN ER	PREGABALIN TAB ER 24HR 165 MG	62540060007530	Generic
PREGABALIN ER	PREGABALIN TAB ER 24HR 330 MG	62540060007540	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to one of the following:

- amitriptyline*
- cyclobenzaprine*
- duloxetine
- gabapentin (generic Neurontin)
- pregabalin immediate-release

Notes	Amitriptyline and cyclobenzaprine are considered to be potentially ina ppropriate medications for use in patients 65 years of age and older. [3, A]

Product Name:Brand Gralise, Brand Gralise Starter Pack, generic gabapentin (generic Gralise)	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
GRALISE	GABAPENTIN (ONCE-DAILY) TAB 300 MG	62540030000320	Brand
GRALISE	GABAPENTIN (ONCE-DAILY) TAB 600 MG	62540030000330	Brand
GRALISE	GABAPENTIN (ONCE-DAILY) TAB PACK 300 MG (9) & 600 MG (24)	62540030006330	Brand
GRALISE	GABAPENTIN (ONCE-DAILY) TAB 450 MG	62540030000325	Brand
GRALISE	GABAPENTIN (ONCE-DAILY) TAB 750 MG	62540030000345	Brand
GRALISE	GABAPENTIN (ONCE-DAILY) TAB 900 MG	62540030000360	Brand
GABAPENTIN	GABAPENTIN (ONCE-DAILY) TAB 300 MG	62540030000320	Generic
GABAPENTIN	GABAPENTIN (ONCE-DAILY) TAB 600 MG	62540030000330	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure or intolerance to generic gabapentin (generic Neurontin)

3 . Endnotes

A. Amitriptyline is part of the Beer's Criteria for potentially inappropriate medication use in older adults (independent of diagnoses or condition) because of its strong anticholinergic and sedation properties while cyclobenzaprine is listed as most muscle relaxants and antispasmodic drugs are poorly tolerated by elderly patients, since these cause anticholinergic adverse effects, sedation, and weakness. [3] However, amitriptyline and cyclobenzaprine have the strongest evidence for efficacy in fibromyalgia amongst the tricyclic antidepressants. [2,4]

4 . References

1. Savella Prescribing Information. Allergan USA, Inc. Irvine, CA. September 2021.
2. Goldenberg DL, Burckhardt C, Crofford L. Management of fibromyalgia syndrome. JAMA. 2004;292(19):2388-95.
3. Fick DM, Semla TP, Steinman M, et al. American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019; 67:674-694. doi: 10.1111/jgs.15767.
4. Clauw DJ. Fibromyalgia: a clinical review. JAMA. 2014;311(15):1547-1555.
5. Lyrica CR Prescribing Information. Pfizer, Inc. New York, NY. June 2020.
6. Gralise Prescribing Information. Almatica Pharma LLC. Morristown, NJ. February 2021.
7. Pregabalin Extended-Release Prescribing Information. Alvogen, Inc. Morristown, NJ. December 2020.

Prior Authorization Guideline

Guideline ID	GL-229182
Guideline Name	New Drug to Market Program - PA
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/15/2011
P&T Revision Date:	11/21/2024

Note:

The purpose of this guideline is to establish policies and procedures on how to handle drugs included on the New Drugs to Market list for clients who opt to implement the New Drug to Market list as a Prior Authorization program to help manage prescription costs; these drugs will receive a general clinical review until the OptumRx P&T Committee can determine whether drug-specific prior authorization criteria are required. This guideline will not apply to Non-Formulary reviews, drugs that are benefit exclusions, drugs with step therapy edits, drugs that require quantity limit review only, or drugs that are not reviewed for prior authorization by OptumRx.

1 . Criteria

Product Name:Drugs included on the New Drug to Market list for which a Drug-Specific Prior Authorization Guideline is Unavailable*

Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
New drug to market			

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

AND

1.1.3 Requested drug will be used at a dose which is within FDA recommendations

OR

1.2 If requested for an off-label indication, the off-label administrative guideline criteria have been met

AND

2 - One of the following:

2.1 If the requested drug has a formulary alternative with the same active ingredient, both of the following:

2.1.1 Patient has experienced intolerance (e.g., allergy to excipient) with a formulary alternative that has the same active ingredient

AND

2.1.2 Patient has tried and failed at least 2 additional formulary alternatives within the same therapeutic class. If only 1 formulary alternative within the therapeutic class is available, the patient must have tried the formulary alternative within the therapeutic class AND 1 additional formulary alternative. If there are no formulary alternatives within the same therapeutic class, the patient must have failed or had contraindication or intolerance to 2 formulary alternatives.

OR

2.2 If the requested drug is a fixed-dose combination product with each individual ingredients available on formulary, both of the following:

2.2.1 Patient has experienced intolerance (e.g., allergy to excipient) with the individual ingredients in the combination product

AND

2.2.2 Patient has tried and failed at least 2 additional formulary alternatives

OR

2.3 If only over-the-counter (OTC) equivalents^ are available, patient has tried and failed or has contraindications or intolerance to 3 OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial]

OR

2.4 If formulary alternatives are available and do not meet above scenarios, patient has tried and failed, or has contraindication or intolerance to at least three formulary alternatives. If only one or only two formulary alternatives are available, the patient must have failed or had contraindications or intolerance to all available formulary alternatives.

OR **2.5** No formulary alternative or OTC equivalent is available to treat the patient's condition	
Notes	* Drug should be reviewed using the drug-specific Prior Authorization guideline if available. If no drug-specific Prior Authorization guideline is available, proceed with the criteria above. This guideline will not apply to Non-Formulary reviews, drugs that are benefit exclusions, drugs with step therapy edits, drugs that require quantity limit review only, or drugs that are not reviewed for prior authorization by OptumRx. ^OTC equivalents refers to any covered or non-covered OTC equivalent product.

2 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228480
Guideline Name	Nexavar (sorafenib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nexavar (sorafenib)
Renal Cell Carcinoma Indicated for the treatment of patients with advanced renal cell carcinoma (RCC). **Hepatocellular Carcinoma** Indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC). **Differentiated Thyroid Carcinoma** Indicated for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

2 . Criteria

Product Name:Brand Nexavar, generic sorafenib

Diagnosis	Renal cell carcinoma
Approval Length	12 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEXAVAR	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Brand
SORAFENIB	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic
SORAFENIB TOSYLATE	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - Trial and failure or intolerance to generic sorafenib (Applies to Brand Nexavar only)

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Renal cell carcinoma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEXAVAR	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Brand
SORAFENIB	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic
SORAFENIB TOSYLATE	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Hepatocellular carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEXAVAR	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Brand
SORAFENIB	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	2153306040032	
SORAFENIB TOSYLATE	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - Trial and failure or intolerance to generic sorafenib (Applies to Brand Nexavar only)

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Hepatocellular carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEXAVAR	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Brand
SORAFENIB	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic
SORAFENIB TOSYLATE	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Differentiated Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEXAVAR	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Brand
SORAFENIB	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic
SORAFENIB TOSYLATE	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic

Approval Criteria

1 - Diagnosis of differentiated thyroid carcinoma

AND

2 - One of the following:

- Locally recurrent disease

- Metastatic disease

AND

3 - Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine (RAI) treatment

AND

5 - Trial and failure or intolerance to generic sorafenib (Applies to Brand Nexavar only)

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Differentiated Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEXAVAR	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Brand
SORAFENIB	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic
SORAFENIB TOSYLATE	SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21533060400320	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. Mean progression-free survival in Study 1 as described in the Nexavar prescribing information indicates a median progression-free survival of 167 days in Nexavar-treated patients with renal cell carcinoma. [1]

4 . References

1. Nexavar Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. August 2023.
2. Brose MS, Nutting CM, Sherman SI, et al. Rationale and design of DECISION: a doubleblind, randomized, placebo-controlled phase III trial evaluating the efficacy and safety of sorafenib in patients with locally advanced or metastatic radioactive iodine (RAI)-refractory, differentiated thyroid cancer. BMC Cancer. 2011;349.
3. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium [internet database]. https://www.nccn.org. Accessed April 3, 2021.
4. National Comprehensive Cancer network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. V.2.2020. NCCN Website. https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 3, 2020.
5. National Comprehensive Cancer network (NCCN) Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. V.2.2021. NCCN Website. https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 3, 2021
6. National Comprehensive Cancer network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. V.1.2021. NCCN Website. https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 3, 2021
7. Sorafenib Prescribing Information. Dr. Reddys Laboratories Inc. Princeton, NJ. November 2022.

Prior Authorization Guideline

Guideline ID	GL-228694
Guideline Name	Nexletol (bempedoic acid) and Nexlizet (bempedoic acid-ezetimibe)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nexletol (bempedoic acid)
HeFH or primary hyperlipidemia Indicated as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). **Established CVD or high risk for a CVD event but without established CVD** Indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with: established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD.
Drug Name: Nexlizet (bempedoic acid-ezetimibe)
HeFH or primary hyperlipidemia Indicated as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

Established CVD or high risk for a CVD event but without established CVD Indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with: established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD.

2 . Criteria

Product Name:Nexletol, Nexlizet	
Diagnosis	Heterozygous familial hypercholesterolemia (HeFH) or primary hyperlipidemia, established cardiovascular disease (CVD) or high risk for a CVD event but without established CVD
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEXLETOL	BEMPEDOIC ACID TAB 180 MG	39380020000320	Brand
NEXLIZET	BEMPEDOIC ACID-EZETIMIBE TAB 180-10 MG	39991002200320	Brand

Approval Criteria

1 - One of the following diagnoses:

- Heterozygous familial hypercholesterolemia (HeFH)
- Primary Hyperlipidemia
- Established cardiovascular disease (CVD) (e.g., coronary artery disease, symptomatic peripheral arterial disease, cerebrovascular atherosclerotic disease)
- At high risk for a CVD event but without established CVD [e.g., diabetes mellitus (type 1 or type 2) in females over 65 years of age or males over 60 years of age]

AND

2 - One of the following:

- Patient has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
- Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
- Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following LDL-C values while on maximally tolerated statin therapy within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL with ASCVD
- LDL-C greater than or equal to 70 mg/dL without ASCVD

AND

4 - One of the following:

4.1 For Nexletol, ONE of the following:

- Patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy as adjunct to maximally tolerated statin therapy
- Patient has a history of contraindication or intolerance to ezetimibe

OR

4.2 For Nexlizet, patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy as adjunct to maximally tolerated statin therapy

Product Name:Nexletol, Nexlizet	
Diagnosis	Heterozygous familial hypercholesterolemia (HeFH) or primary hyperlipidemia, established cardiovascular disease (CVD) or high risk for a CVD event but without established CVD
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEXLETOL	BEMPEDOIC ACID TAB 180 MG	39380020000320	Brand
NEXLIZET	BEMPEDOIC ACID-EZETIMIBE TAB 180-10 MG	39991002200320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in LDL-C levels)

AND

2 - One of the following:

- Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose
- Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

3 . Endnotes

A. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, and repeated every 3 to 12 months as needed. [3]

4 . References

1. Nexletol Prescribing Information. Esperion Therapeutics, Inc. Ann Arbor, MI. March 2024.
2. Nexlizet Prescribing Information. Esperion Therapeutics, Inc. Ann Arbor, MI. March 2024.
3. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.

4. Alonso R, Cuevas A, Cafferata A. Diagnosis and Management of Statin Intolerance. J Atheroscler Thromb. 2019 Mar 1;26(3):207-215. doi: 10.5551/jat.RV17030. Epub 2019 Jan 19. PMID: 30662020; PMCID: PMC6402887.
5. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. J Am Coll Cardiol. 2017;70:1785-1822.
6. Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. N Engl J Med. 2015;372:2387-97.
7. Harada-Shiba M, Arai H, Ishigaki Y, Ishibashi S, Okamura T, Ogura M, Dobashi K, Nohara A, Bujo H, Miyauchi K, Yamashita S, Yokote K; Working Group by Japan Atherosclerosis Society for Making Guidance of Familial Hypercholesterolemia. Guidelines for Diagnosis and Treatment of Familial Hypercholesterolemia 2017. J Atheroscler Thromb. 2018 Aug 1;25(8):751-770. doi: 10.5551/jat.CR003. Epub 2018 Jun 7. PMID: 29877295; PMCID: PMC6099072.
8. Lloyd-Jones D, Morris P, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. J Am Coll Cardiol. 2022 Oct, 80 (14) 1366–1418. https://doi.org/10.1016/j.jacc.2022.07.006

Prior Authorization Guideline

Guideline ID	GL-228695
Guideline Name	Nexviazyme (avalglucosidase alfa-ngpt)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nexviazyme (avalglucosidase alfa-ngpt)
Pompe Disease Indicated for the treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency).

2 . Criteria

Product Name:Nexviazyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEXVIAZYME	AVALGLUCOSIDASE ALFA-NGPT FOR IV SOLN 100 MG	30907722552120	Brand

Approval Criteria

1 - Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: [2, 3]

1.1 Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

OR

1.2 Molecular genetic testing confirms mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.) [A]

AND

3 - Patient is 1 year of age or older

Product Name:Nexviazyme	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEXVIAZYME	AVALGLUCOSIDASE ALFA-NGPT FOR IV SOLN 100 MG	30907722552120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

3 . Endnotes

A. Consensus recommendation based on current clinical guidelines indicate that treatment should be started in patients when they become symptomatic and/or show signs of disease progression [2, 3].

4 . References

1. Nexviazyme Prescribing Information. Genzyme Corporation. Cambridge, MA. September 2023.
2. Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Rev Neurol 2012; 54 (8): 497-507.
3. Kishnani PS, Steiner RD, Bali D, et al. Pompe disease diagnosis and management guideline. Genet Med. May 2006; 8(5): 267–288.

Prior Authorization Guideline

Guideline ID	GL-228914
Guideline Name	Ninlaro (ixazomib citrate)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ninlaro (ixazomib citrate)
Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. Limitations of Use: NINLARO is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials

2 . Criteria

Product Name:Ninlaro	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NINLARO	IXAZOMIB CITRATE CAP 2.3 MG (BASE EQUIVALENT)	21536045100120	Brand
NINLARO	IXAZOMIB CITRATE CAP 3 MG (BASE EQUIVALENT)	21536045100130	Brand
NINLARO	IXAZOMIB CITRATE CAP 4 MG (BASE EQUIVALENT)	21536045100140	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

Product Name:Ninlaro	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NINLARO	IXAZOMIB CITRATE CAP 2.3 MG (BASE EQUIVALENT)	21536045100120	Brand
NINLARO	IXAZOMIB CITRATE CAP 3 MG (BASE EQUIVALENT)	21536045100130	Brand
NINLARO	IXAZOMIB CITRATE CAP 4 MG (BASE EQUIVALENT)	21536045100140	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Ninlaro Prescribing Information. Takeda Pharmaceutical Company Limited. Cambridge, MA. November 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed 12 February, 2024

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233258
Guideline Name	Nityr and Orfadin
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	4/18/2018
P&T Revision Date:	6/19/2024

1 . Indications

Drug Name: Nityr (nitisinone) tablets
Hereditary Tyrosinemia Type 1 (HT-1) Indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.
Drug Name: Brand Orfadin capsules, Brand Orfadin oral suspension, Generic nitisinone capsules
Hereditary Tyrosinemia Type 1 (HT-1) Indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

2 . Criteria

Product Name:Nityr*, Brand Orfadin, Generic nitisinone	
Diagnosis	Hereditary Tyrosinemia type 1 (HT-1)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NITYR	NITISINONE TAB 2 MG	30904045000310	Brand
NITYR	NITISINONE TAB 5 MG	30904045000320	Brand
NITYR	NITISINONE TAB 10 MG	30904045000330	Brand
ORFADIN	NITISINONE CAP 2 MG	30904045000110	Brand
ORFADIN	NITISINONE CAP 5 MG	30904045000120	Brand
ORFADIN	NITISINONE CAP 10 MG	30904045000130	Brand
ORFADIN	NITISINONE CAP 20 MG	30904045000140	Brand
ORFADIN	NITISINONE SUSP 4 MG/ML	30904045001820	Brand
NITISINONE	NITISINONE CAP 2 MG	30904045000110	Generic
NITISINONE	NITISINONE CAP 5 MG	30904045000120	Generic
NITISINONE	NITISINONE CAP 10 MG	30904045000130	Generic
NITISINONE	NITISINONE CAP 20 MG	30904045000140	Generic

Approval Criteria

1 - Diagnosis of hereditary tyrosinemia type 1 (HT-1)

AND

2 - Diagnosis confirmed by the presence of succinylacetone in the plasma or urine [1-3]

AND

3 - Used in combination with dietary restriction of tyrosine and phenylalanine

AND

4 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist
- Other specialist with experience in treating inborn errors of metabolism

AND

5 - Applies to Nityr only; trial and intolerance to brand Orfadin

Notes	*For patients who have difficulties swallowing intact tablets, including pediatric patients, the tablets can be disintegrated in water and admini stered using an oral syringe. If patients can swallow semi-solid foods, the tablets can also be crushed and mixed with applesauce. For prepa ration and administration instructions, see the full prescribing informati on [1].

Product Name:Nityr*, Brand Orfadin, Generic nitisinone	
Diagnosis	Hereditary Tyrosinemia type 1 (HT-1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NITYR	NITISINONE TAB 2 MG	30904045000310	Brand
NITYR	NITISINONE TAB 5 MG	30904045000320	Brand
NITYR	NITISINONE TAB 10 MG	30904045000330	Brand
ORFADIN	NITISINONE CAP 2 MG	30904045000110	Brand
ORFADIN	NITISINONE CAP 5 MG	30904045000120	Brand
ORFADIN	NITISINONE CAP 10 MG	30904045000130	Brand
ORFADIN	NITISINONE CAP 20 MG	30904045000140	Brand
ORFADIN	NITISINONE SUSP 4 MG/ML	30904045001820	Brand

NITISINONE	NITISINONE CAP 2 MG	30904045000110	Generic
NITISINONE	NITISINONE CAP 5 MG	30904045000120	Generic
NITISINONE	NITISINONE CAP 10 MG	30904045000130	Generic
NITISINONE	NITISINONE CAP 20 MG	30904045000140	Generic

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy

AND

2 - Applies to Nityr only; trial and intolerance to brand Orfadin

Notes	*For patients who have difficulties swallowing intact tablets, including pediatric patients, the tablets can be disintegrated in water and administered using an oral syringe. If patients can swallow semi-solid foods, the tablets can also be crushed and mixed with applesauce. For preparation and administration instructions, see the full prescribing information.

3 . References

1. Nityr prescribing information. Cycle Pharmaceuticals Ltd. Cambridge, UK. May 2024.
2. Orfadin prescribing Information. Sobi Inc. Waltham, MA. November 2021.
3. de Laet C, Dionisi-Vici C, Leonard JV, et al. Recommendations for the management of tyrosinaemia type 1. Orphanet J Rare Dis. 2013;8:8.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228698
Guideline Name	Nocdurna (desmopressin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nocdurna (desmopressin acetate sublingual tablet)
Nocturia Indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void. In the Nocdurna clinical trials nocturnal polyuria was defined as night-time urine production exceeding one-third of the 24-hour urine production. Before starting Nocdurna: (1) Evaluate the patient for possible causes for the nocturia, including excessive fluid intake prior to bedtime, and address other treatable causes of nocturia. (2) Confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection, if one has not been obtained previously.

2 . Criteria

Product Name:Nocdurna	
Approval Length	3 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOCDURNA	DESMOPRESSIN ACETATE SUBLINGUAL TAB 27.7 MCG	30201010100710	Brand
NOCDURNA	DESMOPRESSIN ACETATE SUBLINGUAL TAB 55.3 MCG	30201010100715	Brand

Approval Criteria

1 - Diagnosis of nocturia due to nocturnal polyuria

AND

2 - Nighttime urine production exceeds one-third of the 24-hour urine production [A]

AND

3 - Patient wakes at least twice per night on a reoccurring basis to void

AND

4 - Initial serum sodium level prior to initiating therapy is within normal limits of the normal laboratory reference range

AND

5 - One of the following: [B]

5.1 Underlying causes of nocturia have been ruled out (e.g., overactive bladder, benign prostatic hyperplasia (BPH), Parkinson’s disease, excessive bedtime fluid intake)

OR

5.2 Underlying medical causes of nocturia are treated prior to initiating therapy (e.g., use of alpha-adrenergic blockers or 5-alpha reductase inhibitors for BPH, vaginal estrogens for vaginal atrophy)

Product Name:Nocdurna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOCDURNA	DESMOPRESSIN ACETATE SUBLINGUAL TAB 27.7 MCG	30201010100710	Brand
NOCDURNA	DESMOPRESSIN ACETATE SUBLINGUAL TAB 55.3 MCG	30201010100715	Brand

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient has routine monitoring for serum sodium levels

3 . Endnotes

A. In clinical trials, nocturnal polyuria was defined as nighttime urine production exceeding one-third of the 24-hour urine production. [1]
B. Prior to initiating treatment, patients should be evaluated for possible causes of nocturia and to optimize the treatment of underlying conditions that may be contributing to the nocturia. [1]

4 . References

1. Nocdurna Prescribing Information. Antares Pharma, Inc. Ewing, NJ. August 2021.

Prior Authorization Guideline

Guideline ID	GL-228697
Guideline Name	Nocdurna (desmopressin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nocdurna (desmopressin acetate sublingual tablet)
Nocturia Indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void. In the Nocdurna clinical trials nocturnal polyuria was defined as night-time urine production exceeding one-third of the 24-hour urine production. Before starting Nocdurna: (1) Evaluate the patient for possible causes for the nocturia, including excessive fluid intake prior to bedtime, and address other treatable causes of nocturia. (2) Confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection, if one has not been obtained previously.

2 . Criteria

Product Name:Nocdurna	
Approval Length	3 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOCDURNA	DESMOPRESSIN ACETATE SUBLINGUAL TAB 27.7 MCG	30201010100710	Brand
NOCDURNA	DESMOPRESSIN ACETATE SUBLINGUAL TAB 55.3 MCG	30201010100715	Brand

Approval Criteria

1 - Diagnosis of nocturia due to nocturnal polyuria

AND

2 - Nighttime urine production exceeds one-third of the 24-hour urine production [A]

AND

3 - Patient wakes at least twice per night on a reoccurring basis to void

AND

4 - Initial serum sodium level prior to initiating therapy is within normal limits of the normal laboratory reference range

AND

5 - One of the following: [B]

5.1 Underlying causes of nocturia have been ruled out (e.g., overactive bladder, benign prostatic hyperplasia (BPH), Parkinson’s disease, excessive bedtime fluid intake)

OR

5.2 Underlying medical causes of nocturia are treated prior to initiating therapy (e.g., use of alpha-adrenergic blockers or 5-alpha reductase inhibitors for BPH, vaginal estrogens for vaginal atrophy)

Product Name:Nocdurna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOCDURNA	DESMOPRESSIN ACETATE SUBLINGUAL TAB 27.7 MCG	30201010100710	Brand
NOCDURNA	DESMOPRESSIN ACETATE SUBLINGUAL TAB 55.3 MCG	30201010100715	Brand

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient has routine monitoring for serum sodium levels

3 . Endnotes

A. In clinical trials, nocturnal polyuria was defined as nighttime urine production exceeding one-third of the 24-hour urine production. [1]
B. Prior to initiating treatment, patients should be evaluated for possible causes of nocturia and to optimize the treatment of underlying conditions that may be contributing to the nocturia. [1]

4 . References

1. Nocdurna Prescribing Information. Antares Pharma, Inc. Ewing, NJ. August 2021.

Prior Authorization Guideline

Guideline ID	GL-228699
Guideline Name	Non-Essential Drug Program – PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Drugs included on the Non-Essential Drug List*			
Approval Length	14 Day(s)		
Guideline Type	Prior Authorization		
Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - All of the following:

1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

AND

1.3 Requested drug will be used at a dose which is within FDA recommendations

AND

2 - One of the following:

2.1 If the requested drug has an alternative(s) on the same or lower tier** with the same active ingredient, both of the following:

2.1.1 Patient has experienced intolerance (e.g., allergy to excipient) with all same and lower tier alternative(s) that has the same active ingredient if applicable

AND

2.1.2 Patient has tried and failed all same and lower tier alternative(s) within the same therapeutic class. If there are no same or lower tier alternatives within the same therapeutic class, the patient must have failed or had contraindication or intolerance to all same and lower tier alternatives if applicable

OR

2.2 If the requested drug is a fixed-dose combination product with each individual ingredients available on same or lower tier**, both of the following:

2.2.1 Patient has experienced intolerance (e.g., allergy to excipient) with the individual ingredients in the combination product

AND

2.2.2 Patient has tried and failed all same and lower tier alternatives if applicable

OR

2.3 If only Over-The-Counter (OTC) equivalents^ are available, patient has tried and failed or has contraindications or intolerance to all available OTC equivalents. [document drug(s), dose, duration of trial]

OR

2.4 If alternative(s) on the same or lower tier** available and do not meet above scenarios, patient has tried and failed, or has contraindication or intolerance to all same and lower tier alternatives

AND

3 - Submission of records (e.g., chart notes) confirming why the requested drug is expected to provide benefit when the same and lower tier alternative(s) or OTC equivalent(s) has not shown to be effective

Notes	* If being used for any other indication, deny the case for medical nec essity and do not review for off-label use. **Alternatives on the same ti er refers to a requested drug on tier 1. ^OTC equivalents refers to any covered or non-covered OTC equivalent product.

Product Name:Drugs included on the Non-Essential Drug List*	
Approval Length	14 Day(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - All of the following:

1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

AND

1.3 Requested drug will be used at a dose which is within FDA recommendations

AND

2 - One of the following:

2.1 If the requested drug has a lower tier alternative(s) with the same active ingredient, both of the following:

2.1.1 Submission of medical records (e.g., chart notes) confirming patient has experienced intolerance (e.g., allergy to excipient) with all lower tier alternative(s) that has the same active ingredient

AND

2.1.2 Submission of medical records (e.g., chart notes) or paid claims confirming patient has tried and failed all lower tier alternative(s) within the same therapeutic class. If there are no lower tier alternatives within the same therapeutic class, the patient must have failed or had contraindication or intolerance to all lower tier alternatives

OR

2.2 If the requested drug is a fixed-dose combination product with each individual ingredients available on lower tier, both of the following:

2.2.1 Submission of medical records (e.g., chart notes) confirming patient has experienced intolerance (e.g., allergy to excipient) with the individual ingredients in the combination product

AND

2.2.2 Submission of medical records (e.g., chart notes) or paid claims confirming patient has tried and failed all lower tier alternatives

OR

2.3 If only Over-The-Counter (OTC) equivalents^ are available, patient has tried and failed or has contraindications or intolerance to all available OTC equivalents. [document drug(s), dose, duration of trial]

OR

2.4 If lower tier alternatives are available and do not meet above scenarios, submission of medical records (e.g., chart notes) or paid claims confirming patient has tried and failed, or has contraindication or intolerance to all lower tier alternatives

AND

3 - Submission of records (e.g., chart notes) confirming why the requested drug is expected to provide benefit when the lower tier alternative(s) or OTC equivalent(s) has not shown to be effective

Notes	* If being used for any other indication, deny the case for non-formulary and do not review for off-label use. ^OTC equivalents refers to any covered or non-covered OTC equivalent product.

Prior Authorization Guideline

Guideline ID	GL-229123
Guideline Name	Non-Formulary & Excluded Drug Exceptions Process for Drugs of Clinical Concern
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/21/2024

Note:

The purpose of this guideline is to establish policies and procedures on how to handle non-formulary and excluded drugs when continuation of prior therapy (COT) is allowed. Continuation of prior therapy is allowed for drugs used in serious and complex disease states for which therapy needs to be tailored and/or there is significant variability in response among patients, AND change in medication therapy for members stable on established therapy could lead to irreversible disease progression, resistance to therapy, emergency room admission, hospitalization, significant disability, or death. Exceptions to COT may be allowed for drugs where there is limited risk for delays in therapy that may lead to adverse events. Continuation of therapy will not apply in cases where there is an AB-rated generic or interchangeable biosimilar. This guideline will not apply to drug exclusions that do not allow for continuation of prior therapy, drugs with step therapy edits, drugs that require quantity limit review only, or drugs that are not reviewed for prior authorization by OptumRx. ** Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity.**

1 . Criteria

Product Name:Brand Combivir, Brand Emtriva capsules, Brand Epivir, Brand Epzicom, Brand Intelence 100mg and 200mg tablets, Brand Kaletra, Brand Lexiva tablet, Brand Norvir tablets, Brand Retrovir, Brand Reyataz capsules, Brand Sustiva, Brand Symfi, Brand Symfi Lo, Brand Vimpat, Brand Viread 300mg tablets, Brand Ziagen [A]	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VIMPAT	LACOSAMIDE TAB 50 MG	72600036000320	Brand
VIMPAT	LACOSAMIDE TAB 100 MG	72600036000330	Brand
VIMPAT	LACOSAMIDE TAB 150 MG	72600036000340	Brand
VIMPAT	LACOSAMIDE TAB 200 MG	72600036000350	Brand
VIMPAT	LACOSAMIDE IV INJ 200 MG/20ML (10 MG/ML)	72600036002020	Brand
VIMPAT	LACOSAMIDE ORAL SOLUTION 10 MG/ML	72600036002060	Brand
COMBIVIR	LAMIVUDINE-ZIDOVUDINE TAB 150-300 MG	12109902500320	Brand
EPZICOM	ABACAVIR SULFATE-LAMIVUDINE TAB 600-300 MG	12109902200340	Brand
KALETRA	LOPINAVIR-RITONAVIR TAB 100-25 MG	12109902550310	Brand
KALETRA	LOPINAVIR-RITONAVIR TAB 200-50 MG	12109902550320	Brand
KALETRA	LOPINAVIR-RITONAVIR SOLN 400-100 MG/5ML (80-20 MG/ML)	12109902552020	Brand
REYATAZ	ATAZANAVIR SULFATE CAP 200 MG (BASE EQUIV)	12104515200140	Brand
REYATAZ	ATAZANAVIR SULFATE CAP 300 MG (BASE EQUIV)	12104515200150	Brand
LEXIVA	FOSAMPRENAVIR CALCIUM TAB 700 MG (BASE EQUIV)	12104525100330	Brand
LEXIVA	FOSAMPRENAVIR CALCIUM SUSP 50 MG/ML (BASE EQUIV)	12104525101820	Brand
NORVIR	RITONAVIR TAB 100 MG	12104560000320	Brand
NORVIR	RITONAVIR CAP 100 MG	12104560000120	Brand
ZIAGEN	ABACAVIR SULFATE SOLN 20 MG/ML (BASE EQUIV)	12105005102020	Brand
ZIAGEN	ABACAVIR SULFATE TAB 300 MG (BASE EQUIV)	12105005100320	Brand
EMTRIVA	EMTRICITABINE CAPS 200 MG	12106030000120	Brand
EPIVIR	LAMIVUDINE TAB 150 MG	12106060000320	Brand
EPIVIR	LAMIVUDINE TAB 300 MG	12106060000330	Brand

EPIVIR	LAMIVUDINE ORAL SOLN 10 MG/ML	12106060002020	Brand
RETROVIR	ZIDOVUDINE CAP 100 MG	12108085000110	Brand
RETROVIR	ZIDOVUDINE SYRUP 10 MG/ML	12108085001210	Brand
RETROVIR IV INFUSION	ZIDOVUDINE IV SOLN 10 MG/ML	12108085002020	Brand
VIREAD	TENOFOVIR DISOPROXIL FUMARATE TAB 300 MG	12108570100320	Brand
SUSTIVA	EFAVIRENZ TAB 600 MG	12109030000330	Brand
SUSTIVA	EFAVIRENZ CAP 50 MG	12109030000110	Brand
SUSTIVA	EFAVIRENZ CAP 200 MG	12109030000140	Brand
INTELENCE	ETRAVIRINE TAB 100 MG	12109035000320	Brand
INTELENCE	ETRAVIRINE TAB 200 MG	12109035000340	Brand
SYMFI LO	EFAVIRENZ-LAMIVUDINE-TENOFOVIR DF TAB 400-300-300 MG	12109903330330	Brand
SYMFI	EFAVIRENZ-LAMIVUDINE-TENOFOVIR DF TAB 600-300-300 MG	12109903330340	Brand

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Both of the following:

1.1.1.1 Submission of medical records (e.g., chart notes) documenting the patient has lack of adequate clinical response and related symptoms (e.g., allergy to excipient, worsening symptoms) with a formulary alternative that has the same active ingredient

AND

1.1.1.2 One of the following:

1.1.1.2.1 Submission of medical records (e.g., chart notes) or paid claims documenting the patient has tried and failed at least 2 additional formulary alternatives within the same therapeutic class. If only 1 formulary alternative within the therapeutic class is available, the patient must have tried the formulary alternative within the therapeutic class AND 1 additional formulary alternative. If there are no formulary alternatives within the same therapeutic class, the patient must have failed or had contraindication or intolerance to 2 formulary alternatives.

OR

1.1.1.2.2 For continuation of prior therapy

OR

1.1.2 If the requested drug is a fixed-dose combination product with each individual ingredients available on formulary, one of the following:

1.1.2.1 Both of the following:

1.1.2.1.1 Submission of medical records (e.g., chart notes) documenting the patient has lack of adequate clinical response and related symptoms (e.g., allergy to excipient, worsening symptoms) with the individual ingredients in the combination product

AND

1.1.2.1.2 Submission of medical records (e.g., chart notes) or paid claims documenting the patient has tried and failed at least 2 additional formulary alternatives

OR

1.1.2.2 For continuation of prior therapy

OR

1.1.3 One of the following:

1.1.3.1 If formulary alternatives are available and do not meet above scenarios, submission of medical records (e.g., chart notes) or paid claims documenting patient has tried and failed, or has contraindication or intolerance to at least 3 formulary alternatives. If only 1 or only 2 alternatives are available, the patient must have failed or had contraindications or intolerance to all available formulary alternatives (Refer to Table 1 for examples of equivalent formulary alternatives)

OR

1.1.3.2 For continuation of prior therapy

OR

1.1.4 No formulary alternative is available to treat the patient's condition

AND

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.2.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Product Name:Aplenzin, Aptiom, Auvelity, Ayvakit, Brukinsa, Caplyta, Citalopram 30mg capsule, Delstrigo, Elepsia XR, Emsam, Eprontia, Esperoct, Fintepla, Forfivo XL, Bupropion HCL 450mg ER (XL), Genvoya, Ilumya, Jivi, Kcentra, Lexiva solution, Lybalvi, Norvir capsule/packet/solution, Nubeqa, Nuplazid, Brand Oxtellar XR, Generic oxcarbazepine extended - release, Rebinyn, Rylaze, Savaysa, Secuado, Sertraline capsules, Siliq, Spritam, Stribild, Trizivir, Trogarzo, Venlafaxine 112.5mg tablet, Xembify, Zonisade [B]

Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
RYLAZE	ASPARAGINASE ERWINIA CHRYS (RECOMB)-RYWN IM SOLN 10 MG/0.5ML	21250010602020	Brand

CITALOPRAM HYDROBROMIDE	CITALOPRAM HYDROBROMIDE CAP 30 MG	58160020100120	Brand
SERTRALINE HYDROCHLORIDE	SERTRALINE HCL CAP 150 MG	58160070100130	Brand
SERTRALINE HYDROCHLORIDE	SERTRALINE HCL CAP 200 MG	58160070100140	Brand
VENLAFAXINE BESYLATE ER	VENLAFAXINE BESYLATE TAB ER 24HR 112.5 MG	58180090057520	Brand
BUPROPION HYDROCHLORIDE ER (XL)	BUPROPION HCL TAB ER 24HR 450 MG	58300040107545	Generic
FORFIVO XL	BUPROPION HCL TAB ER 24HR 450 MG	58300040107545	Generic
AUVELITY	DEXTROMETHORPHAN HBR-BUPROPION HCL TAB ER 45-105 MG	58999902300420	Brand
SECUADO	ASENAPINE TD PATCH 24 HR 3.8 MG/24HR	59155015008520	Brand
SECUADO	ASENAPINE TD PATCH 24 HR 5.7 MG/24HR	59155015008530	Brand
SECUADO	ASENAPINE TD PATCH 24 HR 7.6 MG/24HR	59155015008540	Brand
LYBALVI	OLANZAPINE-SAMIDORPHAN L-MALATE TAB 5-10 MG	62994802500310	Brand
LYBALVI	OLANZAPINE-SAMIDORPHAN L-MALATE TAB 10-10 MG	62994802500320	Brand
LYBALVI	OLANZAPINE-SAMIDORPHAN L-MALATE TAB 15-10 MG	62994802500330	Brand
LYBALVI	OLANZAPINE-SAMIDORPHAN L-MALATE TAB 20-10 MG	62994802500340	Brand
ELEPSIA XR	LEVETIRACETAM TAB ER 24HR 1000 MG	72600043007550	Brand
ELEPSIA XR	LEVETIRACETAM TAB ER 24HR 1500 MG	72600043007570	Brand
OXTELLAR XR	OXCARBAZEPINE TAB ER 24HR 150 MG	72600046007520	Brand
OXTELLAR XR	OXCARBAZEPINE TAB ER 24HR 300 MG	72600046007530	Brand
OXTELLAR XR	OXCARBAZEPINE TAB ER 24HR 600 MG	72600046007540	Brand
EPRONTIA	TOPIRAMATE ORAL SOLN 25 MG/ML	72600075002020	Brand
ZONISADE	ZONISAMIDE ORAL SUSP 100 MG/5ML (20 MG/ML)	72600090001820	Brand
APLENZIN	BUPROPION HBR TAB ER 24HR 174 MG	58300040207520	Brand
APLENZIN	BUPROPION HBR TAB ER 24HR 348 MG	58300040207530	Brand
APLENZIN	BUPROPION HBR TAB ER 24HR 522 MG	58300040207540	Brand
APTIOM	ESLICARBAZEPINE ACETATE TAB 200 MG	72600024100320	Brand
APTIOM	ESLICARBAZEPINE ACETATE TAB 400 MG	72600024100330	Brand
APTIOM	ESLICARBAZEPINE ACETATE TAB 600 MG	72600024100340	Brand

APTIOM	ESLICARBAZEPINE ACETATE TAB 800 MG	72600024100360	Brand
CAPLYTA	LUMATEPERONE TOSYLATE CAP 10.5 MG	59400022400110	Brand
CAPLYTA	LUMATEPERONE TOSYLATE CAP 21 MG	59400022400115	Brand
CAPLYTA	LUMATEPERONE TOSYLATE CAP 42 MG	59400022400120	Brand
FINTEPLA	FENFLURAMINE HCL ORAL SOLN 2.2 MG/ML	72600028102020	Brand
JIVI	ANTIHEMOPHIL FACT RCMB(BDD-RFVIII PEG-AUCL) FOR INJ 500 UNIT	85100010412130	Brand
JIVI	ANTIHEMOPHIL FACT RCMB(BDD-RFVIII PEG-AUCL)FOR INJ 1000 UNIT	85100010412140	Brand
JIVI	ANTIHEMOPHIL FACT RCMB(BDD-RFVIII PEG-AUCL)FOR INJ 2000 UNIT	85100010412150	Brand
JIVI	ANTIHEMOPHIL FACT RCMB(BDD-RFVIII PEG-AUCL)FOR INJ 3000 UNIT	85100010412160	Brand
KCENTRA	PROTHROMBIN COMPLEX CONC HUMAN FOR INJ KIT 500 UNIT	85100060106420	Brand
KCENTRA	PROTHROMBIN COMPLEX CONC HUMAN FOR INJ KIT 1000 UNIT	85100060106430	Brand
NUBEQA	DAROLUTAMIDE TAB 300 MG	21402425000320	Brand
NUPLAZID	PIMAVANSERIN TARTRATE CAP 34 MG (BASE EQUIVALENT)	59400028200120	Brand
NUPLAZID	PIMAVANSERIN TARTRATE TAB 10 MG (BASE EQUIVALENT)	59400028200310	Brand
REBINYN	COAGULATION FACTOR IX RECOMB GLYCOPEGYLATED FOR INJ 500 UNT	85100028452120	Brand
REBINYN	COAGULATION FACTOR IX RECOMB GLYCOPEGYLATED FOR INJ 1000 UNT	85100028452130	Brand
REBINYN	COAGULATION FACTOR IX RECOMB GLYCOPEGYLATED FOR INJ 2000 UNT	85100028452140	Brand
REBINYN	COAGULATION FACTOR IX RECOMB GLYCOPEGYLATED FOR INJ 3000 UNT	85100028452145	Brand
SAVAYSA	EDOXABAN TOSYLATE TAB 15 MG (BASE EQUIVALENT)	83370030200315	Brand
SAVAYSA	EDOXABAN TOSYLATE TAB 30 MG (BASE EQUIVALENT)	83370030200330	Brand
SAVAYSA	EDOXABAN TOSYLATE TAB 60 MG (BASE EQUIVALENT)	83370030200350	Brand
SPRITAM	LEVETIRACETAM TAB DISINTEGRATING SOLUBLE 250 MG	7260004300G820	Brand
SPRITAM	LEVETIRACETAM TAB DISINTEGRATING SOLUBLE 500 MG	7260004300G830	Brand
SPRITAM	LEVETIRACETAM TAB DISINTEGRATING SOLUBLE 750 MG	7260004300G840	Brand

SPRITAM	LEVETIRACETAM TAB DISINTEGRATING SOLUBLE 1000 MG	7260004300G850	Brand
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 1 GM/5ML	19100020642020	Brand
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 2 GM/10ML	19100020642025	Brand
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 4 GM/20ML	19100020642030	Brand
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 10 GM/50ML	19100020642040	Brand
ESPEROCT	ANTIHEMOPHILIC FACTOR RECOMB GLYCOPEG-EXEI FOR INJ 500 UNIT	85100010352130	Brand
ESPEROCT	ANTIHEMOPHILIC FACTOR RECOMB GLYCOPEG-EXEI FOR INJ 1000 UNIT	85100010352140	Brand
ESPEROCT	ANTIHEMOPHILIC FACTOR RECOMB GLYCOPEG-EXEI FOR INJ 1500 UNIT	85100010352145	Brand
ESPEROCT	ANTIHEMOPHILIC FACTOR RECOMB GLYCOPEG-EXEI FOR INJ 2000 UNIT	85100010352150	Brand
ESPEROCT	ANTIHEMOPHILIC FACTOR RECOMB GLYCOPEG-EXEI FOR INJ 3000 UNIT	85100010352160	Brand
DELSTRIGO	DORAVIRINE-LAMIVUDINE-TENOFOVIR DF TAB 100-300-300 MG	12109903270320	Brand
GENVOYA	ELVITEGRAV-COBIC-EMTRICITAB-TENOFOV AF TAB 150-150-200-10 MG	12109904290315	Brand
STRIBILD	ELVITEGRAV-COBIC-EMTRICITAB-TENOFOVDF TAB 150-150-200-300 MG	12109904300320	Brand
TROGARZO	IBALIZUMAB-UIYK IV SOLN 200 MG/1.33ML (150 MG/ML)	12102240302020	Brand
AYVAKIT	AVAPRITINIB TAB 25 MG	21490009000310	Brand
AYVAKIT	AVAPRITINIB TAB 50 MG	21490009000315	Brand
AYVAKIT	AVAPRITINIB TAB 100 MG	21490009000320	Brand
AYVAKIT	AVAPRITINIB TAB 200 MG	21490009000330	Brand
AYVAKIT	AVAPRITINIB TAB 300 MG	21490009000340	Brand
BRUKINSA	ZANUBRUTINIB CAP 80 MG	21532195000120	Brand
EMSAM	SELEGILINE TD PATCH 24HR 6 MG/24HR	58100027008520	Brand
EMSAM	SELEGILINE TD PATCH 24HR 9 MG/24HR	58100027008530	Brand
EMSAM	SELEGILINE TD PATCH 24HR 12 MG/24HR	58100027008540	Brand
OXCARBAZEPINE ER	OXCARBAZEPINE TAB ER 24HR 150 MG	72600046007520	Generic
OXCARBAZEPINE ER	OXCARBAZEPINE TAB ER 24HR 300 MG	72600046007530	Generic

OXCARBAZEPINE ER	OXCARBAZEPINE TAB ER 24HR 600 MG	72600046007540	Generic

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 For continuation of prior therapy

OR

1.1.2 Both of the following:

1.1.2.1 Submission of medical records (e.g., chart notes) documenting the patient has lack of adequate clinical response and related symptoms (e.g., allergy to excipient, worsening symptoms) with a formulary alternative that has the same active ingredient

AND

1.1.2.2 Submission of medical records (e.g., chart notes) or paid claims documenting the patient has tried and failed at least 2 additional formulary alternatives within the same therapeutic class. If only 1 formulary alternative within the therapeutic class is available, the patient must have tried the formulary alternative within the therapeutic class AND 1 additional formulary alternative. If there are no formulary alternatives within the same therapeutic class, the patient must have failed or had contraindication or intolerance to 2 formulary alternatives.

OR

1.1.3 If the requested drug is a fixed-dose combination product with each individual ingredients available on formulary, both of the following:

1.1.3.1 Submission of medical records (e.g., chart notes) documenting the patient has lack of adequate clinical response and related symptoms (e.g., allergy to excipient, worsening symptoms) with the individual ingredients in the combination product

AND

1.1.3.2 Submission of medical records (e.g., chart notes) or paid claims documenting the patient has tried and failed at least 2 additional formulary alternatives

OR

1.1.4 If formulary alternatives are available and do not meet above scenarios, submission of medical records (e.g., chart notes) or paid claims documenting patient has tried and failed, or has contraindication or intolerance to at least 3 formulary alternatives. If only 1 or only 2 alternatives are available, the patient must have failed or had contraindications or intolerance to all available formulary alternatives (Refer to Table 1 for examples of equivalent formulary alternatives)

OR

1.1.5 No formulary alternative is available to treat the patient's condition

AND

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.2.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

2 . Background

Benefit/Coverage/Program Information

Table 1. Formulary Alternatives for Exclusion Drugs of Clinical Concern

Therapeutic Category	Excluded Medication	Preferred Formulary Altern (*May require PA)
Anticonvulsants	Fintepla (fenfluramine)	• **Valproic acid or clob** • **Diacomit (stiripento Epidiolex (cannabid lamotrigine, topiram zonisamide, levetira Briviact (brivaraceta**
Anticonvulsants	Oxtellar XR (oxcarbazepine extended-release)	• **Generic oxcarbazep**
Anticonvulsants	Aptiom (eslicarbazepine)	• **Generic oxcarbazep tablets**
Anticonvulsants	Zonisade (zonisamide oral suspension)	• **Generic zonisamide**
Anticonvulsants	Brand Vimpat (lacosamide)	• **Generic lacosamide**
Anticonvulsants	Elepsia XR (levetiracetam ER)	• **generic levet ER**
Anticonvulsants	Eprontia (topiramate oral solution)	• **Generic topiramate**
Antidepressants	Aplenzin (bupropion hydrobromide extended-release) Forfivo XL (bupropion hydrochloride extended-release) Brand Bupropion XL 450mg	• **Generic bupropion X products**

Antidepressants	Auvelity (dextromethorphan/bupropion ER 45-105 MG) Emsam (selegiline transdermal system)	• **Generic bupropion** • **Generic citalopram tablet** • **Generic desvenlafaxine ER** • **Generic duloxetine** • **Generic escitalopram** • **Generic fluoxetine** • **Generic mirtazapine** • **Generic paroxetine, Generic paroxetine ER** • **Generic sertraline tablet/solution** • **Generic venlafaxine, Generic venlafaxine ER**
Antidepressants	Brand Citalopram 30mg capsule	• **Generic citalopram tablet**
Antidepressants	Brand Sertraline capsule	• **Generic sertraline tablet**
Antidepressants	Brand Venlafaxine 112.5mg tablet	• **Generic venlafaxine** • **Generic venlafaxine ER**
Antipsychotics	Secuado (asenapine patch)	• **Generic aripiprazole** • **Generic asenapine** • **Generic clozapine** • **Generic olanzapine tablet** • **Generic paliperidone ER** • **Generic quetiapine** • **Generic risperidone** • **Generic ziprasidone**
Antipsychotics, Atypical	Caplyta (lumateperone)	• **Generic atypical antipsychotics (e.g., aripiprazole, Generic asenapine sublingual tablet, clozapine, olanzapine, paliperidone, quetiapine IR/ER, risperidone, ziprasidone)**
Antivirals	Reyataz (atazanavir sulfate) capsules	• **Generic atazanavir sulfate capsules**

Antivirals	Lexiva (fosamprenavir calcium)	• **Generic fosamprenavir calcium**
Antivirals	Norvir (ritonavir) tablets	• **Generic ritonavir tablets**
Antivirals	Ziagen (abacavir sulfate)	• **Generic abacavir sulfate**
Antivirals	Emtriva (emtricitabine) capsules	• **Generic emtricitabine capsules**
Antivirals	Epivir (lamivudine)	• **Generic lamivudine**
Antivirals	Retrovir (zidovudine)	• **Generic zidovudine**
Antivirals	Viread (tenofovir disoproxil fumarate) tablets	• **Generic tenofovir disoproxil fumarate tablets**
Antivirals	Sustiva (efavirenz)	• **Generic efavirenz**
Antivirals	Intelence (etravirine) 100 mg, 200 mg	• **Generic etravirine**
Antivirals	Viramune XR (nevirapine)	• **Generic nevirapine ER**
Antivirals	Epzicom (abacavir sulfate-lamivudine)	• **Generic abacavir sulfate-lamivudine**
Antivirals	Combivir (lamivudine-zidovudine)	• **Generic lamivudine-zidovudine**
Antivirals	Kaletra (lopinavir-ritonavir)	• **Generic lopinavir-ritonavir**
Antivirals	Trizivir (abacavir sulfate-lamivudine-zidovudine)	• **Generic abacavir sulfate-lamivudine-zidovudine**
Antivirals	Delstrigo (doravirine-lamivudine-tenofovir df)	• **No alternative available**
Antivirals	Symfi (efavirenz-lamivudine-tenofovir df), Symfi Lo (efavirenz-lamivudine-tenofovir df)	• **Generic efavirenz-lamivudine-tenofovir df**
Antivirals	Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide)	• **No alternative available**
Antivirals	Stribild (elvitegravir-cobicistat-emtricitabine-tenofovir df)	• **No alternative available**
Antivirals	Trogarzo (ibalizumab injection)	• **No alternative available**
Central Nervous System	Lybalvi (olanzapine and samidorphan)	• **Generic aripiprazole** • **Generic asenapine**

		• **Generic clozapine** • **Generic olanzapine** • **Generic paliperidone** • **Generic quetiapine IR/ER** • **Generic risperidone** • **Generic ziprasidone**
Hemophilia Agents	Esperoct (antihemophilic factor [recombinant], glycopegylated-exei) Jivi (antihemophilic factor [recombinant], pegylated-aucl)	• **Adynovate (antihemophilic factor [recombinant] pegylated)** • **Afstyla (antihemophilic factor [recombinant], single chain)** • **Eloctate (antihemophilic factor [recombinant], Fc fusion protein)**
Immunological Agents	Xembify [immune globulin subcutaneous (human)- klhw]	• **Cuvitru [immune globulin (human)]***
Oncology Agents	Rylaze [asparaginase erwinia chrysanthemi (recombinant)-rywn]	• **Generic oncaspar**
Oncology Agents	Brukinsa (zanubrutinib)	• **No alternative available**

3 . Endnotes

A. Target drugs are brand drugs with AB-rated generics available. Continuation of prior therapy is not required for the switch between brand and its AB-rated generic since pharmacies can automatically switch to the generic at point of sale level.
B. Target drugs are brand drugs without AB-rated generics available. Continuation of prior therapy is allowed for target drugs.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-229142
Guideline Name	Non-formulary Descovy and Truvada
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/21/2020
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Descovy (emtricitabine/tenofovir alafenamide)
Treatment of HIV-1 Infection Indicated in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35kg. Indicated in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg. **HIV-1 Pre-exposure Prophylaxis (PrEP)** Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of human immunodeficiency virus-1 (HIV-1) infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP. Limitations of Use: The indication does not include use of Descovy in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

Drug Name: Truvada (emtricitabine/tenofovir disoproxil fumarate)
Treatment of HIV-1 Infection Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg. **HIV-1 Pre-Exposure Prophylaxis (PrEP)** Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test immediately prior to initiating Truvada for HIV-1 PrEP. The dosage of TRUVADA for HIV-1 PrEP is one tablet (containing 200 mg of FTC and 300 mg of TDF) once daily.

2 . Criteria

Product Name:Descovy	
Diagnosis	Treatment of HIV Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DESCOVY	EMTRICITABINE-TENOFOVIR ALAFENAMIDE FUMARATE TAB 200-25 MG	12109902290320	Brand
DESCOVY	EMTRICITABINE-TENOFOVIR ALAFENAMIDE FUMARATE TAB 120-15 MG	12109902290310	Brand

Approval Criteria

1 - Currently used for the treatment of HIV infection

Product Name:Brand Truvada	
Diagnosis	Treatment of HIV Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

TRUVADA	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TAB 200-300 MG	12109902300320	Brand
TRUVADA	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TAB 100-150 MG	12109902300308	Brand
TRUVADA	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TAB 133-200 MG	12109902300312	Brand
TRUVADA	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TAB 167-250 MG	12109902300316	Brand

Approval Criteria

1 - Using for the treatment of HIV infection

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial of or intolerance to generic emtricitabine/tenofovir disoproxil fumarate (generic Truvada)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Descovy 200/25 mg*, Brand Truvada 200/300 mg*	
Diagnosis	HIV Pre-exposure Prophylaxis (PrEP)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DESCOVY	EMTRICITABINE-TENOFOVIR ALAFENAMIDE FUMARATE TAB 200-25 MG	12109902290320	Brand
TRUVADA	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TAB 200-300 MG	12109902300320	Brand

Approval Criteria **1** - Currently used for HIV Pre-exposure Prophylaxis (PrEP) **AND** **2** - Submission of medical records (e.g., chart notes) confirming patient has a history of intolerance or contraindication to generic Truvada 200/300 mg (emtricitabine/tenofovir disoproxil fumarate)	
Notes	Note: *If patient meets criteria above, please approve at GPI-14.

3 . References

1. Descovy Prescribing Information. Gilead Sciences, Inc. Foster City, CA. January 2022.
2. Truvada Prescribing Information. Gilead Sciences, Inc. Foster City, CA. April 2024.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228482
Guideline Name	Non-Solid Oral Dosage Forms
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Norliqva	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORLIQVA	AMLODIPINE BESYLATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT)	34000003102020	Brand

Approval Criteria

1 - One of the following:

1.1 Requested drug is FDA-approved for the condition being treated

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - Patient is unable to swallow a solid dosage form (e.g., oral tablet, capsule) due to one of the following:

- Age
- Physical impairment (e.g., difficulties with motor or oral coordination)
- Dysphagia
- Patient is using a feeding tube or nasal gastric tube

Product Name:Atorvaliq, Gloperba, Likmez, generic spironolactone suspension	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ATORVALIQ	ATORVASTATIN CALCIUM SUSP 20 MG/5ML (4MG/ML) (BASE EQUIV)	39400010101810	Brand
LIKMEZ	METRONIDAZOLE SUSP 500 MG/5ML	16000035001850	Brand
SPIRONOLACTONE	SPIRONOLACTONE SUSP 25 MG/5ML	37500020001820	Generic
GLOPERBA	COLCHICINE ORAL SOLN 0.6 MG/5ML	68000020002060	Brand

Approval Criteria

1 - One of the following:

1.1 Requested drug is FDA-approved for the condition being treated

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to a generic equivalent of the requested drug in a solid dosage form

OR

2.2 Patient is unable to swallow a solid dosage form (e.g., oral tablet, capsule) due to one of the following:

- Age
- Physical impairment (e.g., difficulties with motor or oral coordination)
- Dysphagia
- Patient is using a feeding tube or nasal gastric tube

Product Name:Jylamvo, Xatmep, Zonisade	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZONISADE	ZONISAMIDE ORAL SUSP 100 MG/5ML (20 MG/ML)	72600090001820	Brand
JYLAMVO	METHOTREXATE ORAL SOLN 2 MG/ML	21300050002075	Brand
XATMEP	METHOTREXATE ORAL SOLN 2.5 MG/ML	21300050002080	Brand

Approval Criteria

1 - One of the following:

1.1 Requested drug is FDA-approved for the condition being treated

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to a generic equivalent of the requested drug in a solid dosage form

OR

2.2 Patient is unable to swallow a solid dosage form (e.g., oral tablet, capsule) due to one of the following:

- Age
- Physical impairment (e.g., difficulties with motor or oral coordination)
- Dysphagia
- Patient is using a feeding tube or nasal gastric tube

OR

2.3 For continuation of prior therapy

Prior Authorization Guideline

Guideline ID	GL-233375
Guideline Name	Non-steroidal Anti-Inflammatory Agents - PA, ST
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	11/18/2008
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Cambia (diclofenac) powder
Migraine Indicated for the acute treatment of migraine attacks with or without aura in adults (18 years of age or older). Limitations of use: Cambia is not indicated for the prophylactic therapy of migraine. The safety and effectiveness of Cambia have not been established for cluster headache, which is present in an older, predominantly male population.
Drug Name: Celebrex (celecoxib)
Multiple Indicated for: 1) Osteoarthritis (OA) 2) Rheumatoid Arthritis (RA) 3) Juvenile Rheumatoid Arthritis (JRA) in patients 2 years of age or older 4) Ankylosing Spondylitis (AS) 5) Acute Pain 6) Primary Dysmenorrhea
Drug Name: Sprix (ketorolac tromethamine) nasal spray
Moderate to moderately severe pain Indicated in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the

opioid level. Limitations of Use: Sprix is not for use in pediatric patients less than 2 years of age.
Drug Name: Tivorbex (indomethacin) capsules
Mild to moderate pain Indicated for treatment of mild to moderate acute pain in adults.
Drug Name: Pennsaid (diclofenac sodium) topical solution
Osteoarthritis (OA) Indicated for the treatment of the pain of osteoarthritis of the knee(s).
Drug Name: Indocin
Multiple Indications Indicated for the treatment for the following: moderate to severe rheumatoid arthritis including acute flare of chronic disease, moderate to severe ankylosing spondylitis, moderate to severe osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) or acute gouty arthritis.
Drug Name: Vivlodex
Osteoarthritis (OA) Indicated for the treatment of osteoarthritis (OA) pain.
Drug Name: Zorvolex (diclofenac)
Pain Indicated for the treatment of mild to moderate acute pain and management of osteoarthritis (OA) pain.
Drug Name: Lofena
Primary dysmenorrhea, mild to moderate pain, osteoarthritis, and rheumatoid arthritis Indicated for treatment of primary dysmenorrhea, for relief of mild to moderate pain, for relief of the signs and symptoms of osteoarthritis, for the relief of the signs and symptoms of rheumatoid arthritis.
Drug Name: Meloxicam oral suspension 7.5mg/5mL
Multiple Indicated for: 1) Osteoarthritis (OA) 2) Rheumatoid Arthritis (RA) 3) Juvenile Rheumatoid Arthritis (JRA) in patients 2 years of age or older
Drug Name: Zipsor (diclofenac potassium)
Mild to moderate acute pain Indicated for relief of mild to moderate acute pain in adult and pediatric patients 12 years of age and older.
Drug Name: Indomethacin Suspension 25mg/5ml
Multiple Indications Indicated for the treatment for the following: moderate to severe rheumatoid arthritis including acute flare of chronic disease, moderate to severe ankylosing

spondylitis, moderate to severe osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) or acute gouty arthritis.

Drug Name: Tolectin (tolmetin)

Multiple Indications Indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis. TOLECTIN tablets are indicated in the treatment of acute flares and the long-term management of the chronic disease. Indicated for treatment of juvenile rheumatoid arthritis. The safety and effectiveness of TOLECTIN tablets have not been established in pediatric patients under 2 years of age.

Drug Name: Fenopron

Multiple Indications Indicated for: (1) relief of mild to moderate pain in adults (2) relief of the signs and symptoms of rheumatoid arthritis (RA) (3) relief of the signs and symptoms of osteoarthritis (OA)

Drug Name: Dolobid

Symptomatic Treatment Indicated for acute or long-term use for symptomatic treatment of the following: (1) Mild to moderate pain (2) Osteoarthritis (3) Rheumatoid arthritis

2 . Criteria

Product Name:Sprix nasal spray, Brand Ketorolac nasal spray	
Approval Length	5 Days [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPRIX	KETOROLAC TROMETHAMINE NASAL SPRAY 15.75 MG/SPRAY	66100037102090	Brand
KETOROLAC TROMETHAMINE	KETOROLAC TROMETHAMINE NASAL SPRAY 15.75 MG/SPRAY	66100037102090	Generic

Approval Criteria

1 - Diagnosis of moderate to moderately severe pain

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to oral ketorolac* tablets

OR

2.2 Patient is unable to take medications orally

Notes	*Ketorolac is recommended only for patients less than 65 years old. [B, C]

Product Name:Brand Pennsaid topical solution, Generic diclofenac topical solution	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PENNSAID	DICLOFENAC SODIUM SOLN 2%	90210030302030	Brand
DICLOFENAC SODIUM	DICLOFENAC SODIUM SOLN 1.5%	90210030302025	Generic
DICLOFENAC SODIUM	DICLOFENAC SODIUM SOLN 2%	90210030302030	Generic

Approval Criteria

1 - Diagnosis of osteoarthritis of the knee(s)

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to at least two prescription strength oral NSAIDs (e.g., diclofenac, diclofenac ER, ibuprofen, indomethacin, etc.)

OR

2.2 Documented swallowing disorder

OR

2.3 History of peptic ulcer disease/gastrointestinal bleed

OR

2.4 Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g., use of anticoagulants, chronic corticosteroids)

AND

3 - Trial and failure, contraindication, or intolerance to both of the following: (applies to Brand Pennsaid only)

- generic topical diclofenac 1.5% solution
- generic topical diclofenac 2% solution

Product Name:Brand Pennsaid topical solution, Generic diclofenac topical solution	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DICLOFENAC SODIUM	DICLOFENAC SODIUM SOLN 1.5%	90210030302025	Generic
PENNSAID	DICLOFENAC SODIUM SOLN 2%	90210030302030	Brand
DICLOFENAC SODIUM	DICLOFENAC SODIUM SOLN 2%	90210030302030	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response (e.g., improvement in pain symptoms of osteoarthritis) to therapy

Product Name:Tivorbex*, Brand Diclofenac 50mg, Brand Indomethacin 20mg*, Cambia**^, Brand Celebrex, Indocin*, Lofena, Vivlodex, Zorvolex, Brand diclofenac 35mg capsule, Meloxicam oral suspension 7.5mg/5mL, Brand Zipsor, generic diclofenac 25mg capsule, Generic Indomethacin Suspension 25mg/5ml*, Tolectin,Dolobid, Fenopron	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TIVORBEX	INDOMETHACIN CAP 20 MG	66100030000104	Brand
TIVORBEX	INDOMETHACIN CAP 40 MG	66100030000107	Brand
CAMBIA	DICLOFENAC POTASSIUM PACKET 50 MG	67600040103020	Brand
VIVLODEX	MELOXICAM CAP 5 MG	66100052000115	Brand
VIVLODEX	MELOXICAM CAP 10 MG	66100052000125	Brand
ZORVOLEX	DICLOFENAC CAP 18 MG	66100007000120	Brand
ZORVOLEX	DICLOFENAC CAP 35 MG	66100007000130	Brand
INDOCIN	INDOMETHACIN SUSP 25 MG/5ML	66100030001805	Brand
INDOCIN	INDOMETHACIN SUPPOS 50 MG	66100030005205	Brand
INDOMETHACIN CAP 20 MG	INDOMETHACIN CAP 20 MG	66100030000104	Brand
DICLOFENAC	DICLOFENAC CAP 35 MG	66100007000130	Generic
LOFENA	DICLOFENAC POTASSIUM TAB 25 MG	66100007100320	Brand
MELOXICAM	MELOXICAM SUSP 7.5 MG/5ML	66100052001820	Generic
DICLOFENAC POTASSIUM	DICLOFENAC POTASSIUM CAP 25 MG	66100007100120	Generic
ZIPSOR	DICLOFENAC POTASSIUM CAP 25 MG	66100007100120	Brand
CELEBREX	CELECOXIB CAP 50 MG	66100525000110	Brand
CELEBREX	CELECOXIB CAP 100 MG	66100525000120	Brand
CELEBREX	CELECOXIB CAP 200 MG	66100525000130	Brand

CELEBREX	CELECOXIB CAP 400 MG	66100525000140	Brand
DICLOFENAC POTASSIUM	DICLOFENAC POTASSIUM (MIGRAINE) PACKET 50 MG	67600040103020	Generic
INDOMETHACIN	INDOMETHACIN SUSP 25 MG/5ML	66100030001805	Generic
TOLECTIN 600	TOLMETIN SODIUM TAB 600 MG	66100090100320	Brand
DOLOBID	DIFLUNISAL TAB 250 MG	64100050000305	Brand
FENOPRON	FENOPROFEN CALCIUM CAP 300 MG	66100010100110	Brand

Approval Criteria

1 - Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:

- diclofenac potassium tab or diclofenac sodium
- diflunisal
- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meclofenamate
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam
- sulindac
- tolmetin
- celecoxib

Notes	*Per the American Geriatrics Society 2023 updated Beers criteria, ind omethacin is not recommended for patients greater than or equal to 6 5 years old [B] **Per the American Geriatrics Society 2023 updated B eers criteria, chronic use of NSAIDs, including diclofenac, is not reco mmended for patients greater than or equal to 65 years old unless oth er alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol) [B] ^Product may be excluded depending on the plan.

3 . Endnotes

A. The total duration of use of Sprix alone or sequentially with other formulations of ketorolac (IM/IV or oral) must not exceed 5 days because of the potential for increasing the frequency and severity of adverse reactions associated with the recommended doses. Treat patients for the shortest duration possible, and do not exceed 5 days of therapy with Sprix. [1]
B. This drug is included on the 2023 Beers Criteria for Potentially Inappropriate Medication Use in Older Adults greater than or equal to 65 years old. [3]
C. This drug is included on the 2013 Health Plan Employer Data and Information Set (HEDIS) list of high-risk medications in the elderly (greater than or equal to 65 years old) [4]

4 . References

1. Sprix prescribing information. Zyla Life Sciences US Inc. Wayne, PA. July 2023.
2. Pennsaid prescribing information. Horizon Therapeutics USA, Inc. Lake Forest, IL. February 2022.
3. 2023 American Geriatrics Society Beers Criteria® Update Expert Panel. American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2023; 71(7): 2052-2081.
4. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed March 9, 2022.
5. Tivorbex prescribing information. Iroko Pharmaceuticals LLC, Philadelphia, PA. January 2020.
6. Cambia prescribing information. Depomed, Inc, Newark, CA. October 2019.
7. Vivlodex prescribing information. Egalet US Inc. Wayne PA. April 2021.
8. Indocin prescribing information. Iroko Pharmaceuticals, LLC. Philadelphia, PA. October 2018.
9. Zorvolex prescribing information. Zyla Life Sciences US Inc. Wayne, PA. April 2021.
10. Lofena Prescribing Information. Carwin Pharmaceutical Associates, LLC. Hazlet, NJ. July 2021.
11. Diclofenac Sodium Solution Prescribing Information. Apotex Corporation. Weston, FL. April 2022.
12. Meloxicam Oral Suspension Prescribing Information. Avondale Pharmaceuticals, LLC. Birmingham, AL. January 2024.
13. Indomethacin Suspension Prescribing Information. ANI Pharmaceuticals Inc, Baudette, MN 56623. January 2024.
14. Tolectin prescribing information. Poly Pharmaceuticals, Inc, Owens Cross Roads, AL 35763. February 2024.
15. Fenopron Prescribing Information. Galt Pharmaceuticals, LLC. Atlanta, GA. September 2024.

5 . Revision History

Date	Notes
3/13/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-228701
Guideline Name	Northera (droxidopa)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Northera (droxidopa)
Neurogenic orthostatic hypotension (NOH) Indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (Parkinson's disease [PD], multiple system atrophy and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been established. The continued effectiveness of Northera should be assessed periodically.

2 . Criteria

Product Name:Brand Northera, Generic droxidopa	
Approval Length	1 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORTHERA	DROXIDOPA CAP 100 MG	38700030000130	Brand
NORTHERA	DROXIDOPA CAP 200 MG	38700030000140	Brand
NORTHERA	DROXIDOPA CAP 300 MG	38700030000150	Brand
DROXIDOPA	DROXIDOPA CAP 100 MG	38700030000130	Generic
DROXIDOPA	DROXIDOPA CAP 200 MG	38700030000140	Generic
DROXIDOPA	DROXIDOPA CAP 300 MG	38700030000150	Generic

Approval Criteria

1 - Diagnosis of symptomatic neurogenic orthostatic hypotension (NOH)

AND

2 - NOH is caused by one of the following conditions:

- Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, pure autonomic failure)
- Dopamine beta-hydroxylase deficiency
- Non-diabetic autonomic neuropathy

AND

3 - Prescribed by or in consultation with one of the following specialists: [2, A]

- Cardiologist
- Neurologist
- Nephrologist

AND

4 - Attempt has been made to manage NOH through at least one non-pharmacologic intervention (e.g., use of compression stockings/abdominal binder, increasing salt/fluid intake,

patient participates in regular exercise, discontinue or reduce hypotensive or antihypertensive medications) [2, 4, 5, B]

AND

5 - Trial and failure, contraindication, or intolerance to one of the following agents:

- Fludrocortisone acetate [2, 3]
- Midodrine [2, 3]

Product Name:Brand Northera, Generic droxidopa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORTHERA	DROXIDOPA CAP 100 MG	38700030000130	Brand
NORTHERA	DROXIDOPA CAP 200 MG	38700030000140	Brand
NORTHERA	DROXIDOPA CAP 300 MG	38700030000150	Brand
DROXIDOPA	DROXIDOPA CAP 100 MG	38700030000130	Generic
DROXIDOPA	DROXIDOPA CAP 200 MG	38700030000140	Generic
DROXIDOPA	DROXIDOPA CAP 300 MG	38700030000150	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

3 . Endnotes

A. Per consultant recommendation, prescribers who are best able to manage blood pressure or neurological conditions, like NOH, include cardiologists, neurologists, and nephrologists. [4]
B. According to international treatment guidelines, as well as per consultant recommendation, NOH should be managed non-pharmacologically before using

medications, such as fludrocortisone, midodrine, or droxidopa, to treat NOH directly. This requirement of non-pharmacologic intervention is not possible for Medicare due to benefit design, and will therefore be applicable to Commercial plans only. [2, 4, 5]

4 . References

1. Northera Prescribing Information. Lundbeck. Deerfield, IL. July 2019
2. Berger MJ, Kimpinski K. A practical guide to the treatment of neurogenic orthostatic hypotension. Can J Neurol Sci. 2014;41:156-163.
3. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Accessed March 7, 2022
4. Per Clinical Consultation with a Neurologist. July 7, 2014.
5. Freeman R. Neurogenic orthostatic hypotension. N Engl J Med. 2008; 358:615-24.

Prior Authorization Guideline

Guideline ID	GL-229185
Guideline Name	Nourianz (istradefylline)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/21/2024
P&T Revision Date:	11/16/2023

1 . Indications

Drug Name: Nourianz (istradefylline)
Parkinson's Disease Indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off' episodes.

2 . Criteria

Product Name:Nourianz	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOURIANZ	ISTRADEFYLLINE TAB 20 MG	73401025000320	Brand
NOURIANZ	ISTRADEFYLLINE TAB 40 MG	73401025000340	Brand

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing "off" episodes

AND

3 - Used in combination with carbidopa/levodopa at a maximally tolerated dose [A,1,2]

AND

4 - Trial and failure, contraindication or intolerance to two of the following [A,B,1-4]:

- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT Inhibitor (e.g., entacapone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Nourianz	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOURIANZ	ISTRADEFYLLINE TAB 20 MG	73401025000320	Brand
NOURIANZ	ISTRADEFYLLINE TAB 40 MG	73401025000340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Used in combination with carbidopa/levodopa [A,1,2]

3 . Endnotes

A. Patients included in the pivotal trials continued levodopa/carbidopa treatment throughout study duration, with or without other adjunctive agents, including COMT inhibitors, MAO-B inhibitors, and dopamine agonists. Of the 195 patients of a North American phase IIb trial, 86% of patients were on adjunct dopamine agonists and 41% were on adjunct COMT inhibitors. Similarly, amongst the combined 967 patients enrolled in the other 3 trials (1 North American, 2 Japanese), about 90% were on adjunctive treatment regimens. [1, 2]
B. Management of “off” episodes is individualized to patient response and presentation, which fluctuate and change with disease progression. A 2018 evidence-based medicine review on the treatment of motor fluctuations in Parkinson’s disease recommended MAO-B inhibitors, dopamine agonists, and COMT inhibitors as clinically useful and efficacious, whereas Nourianz was recommended as possibly useful and only likely efficacious. [3, 4]

4 . References

1. Nourianz Prescribing Information. Kyowa Kirin, Inc. Bedminster, NJ. May 2020.
2. Isaacson SH, Bette S, Pahwa R. Istradefylline for off episodes in Parkinson’s disease: A US perspective of common clinical scenarios. Degenerative Neurological and Neuromuscular Disease. 2023;12:97-109.

3. Masood N, Jimenez-Shahed J. Effective management of “off” episodes in Parkinson’s disease: Emerging treatment strategies and unmet clinical needs. Neuropsychiatric Disease and Treatment. 2023;19:247-66.
4. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and Movement Disorder Society evidence-based medicine review: update on treatments for the motor symptoms of Parkinson’s disease. Movement Disorders. 2018;33(8):1248-66.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228486
Guideline Name	Nplate (romiplostim)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nplate (romiplostim)
Immune Thrombocytopenia (ITP) Indicated for the treatment of thrombocytopenia in adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and in pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Limitations of Use: - Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP. - Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding. - Nplate should not be used in an attempt to normalize platelet counts. **Hematopoietic Syndrome of Acute Radiation Syndrome** Indicated to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation.

2 . Criteria

Product Name:Nplate	
Diagnosis	Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NPLATE	ROMIPLOSTIM FOR INJ 250 MCG	82405060002120	Brand
NPLATE	ROMIPLOSTIM FOR INJ 500 MCG	82405060002130	Brand
NPLATE	ROMIPLOSTIM FOR INJ 125 MCG	82405060002110	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Immune thrombocytopenia (ITP) [A]
- Relapsed/refractory ITP [4]

AND

2 - Baseline platelet count is less than 30,000/mcL [2-4]

AND

3 - Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [2]

- Corticosteroids (e.g., dexamethasone, prednisone)
- Immune globulins (e.g., Gammaplex, Gammagard S/D)

- Splenectomy

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Nplate	
Diagnosis	Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NPLATE	ROMIPLOSTIM FOR INJ 250 MCG	82405060002120	Brand
NPLATE	ROMIPLOSTIM FOR INJ 500 MCG	82405060002130	Brand
NPLATE	ROMIPLOSTIM FOR INJ 125 MCG	82405060002110	Brand

Approval Criteria

1 - Patient demonstrates positive response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding

Product Name:Nplate	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NPLATE	ROMIPLOSTIM FOR INJ 250 MCG	82405060002120	Brand
NPLATE	ROMIPLOSTIM FOR INJ 500 MCG	82405060002130	Brand
NPLATE	ROMIPLOSTIM FOR INJ 125 MCG	82405060002110	Brand

Approval Criteria

1 - Diagnosis of hematopoietic syndrome of acute radiation syndrome

AND

2 - Patient is acutely exposed to myelosuppressive doses of radiation

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

3 . Endnotes

A. ITP has previously been called idiopathic thrombocytopenic purpura, immune thrombocytopenic purpura, or autoimmune thrombocytopenic purpura (AITP). These terms have been replaced by "immune thrombocytopenia" to reflect the known autoantibody mechanism and the absence of purpura in some patients. [5]

4 . References

1. Nplate Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2022.
2. Kuter DJ, Bussel JB, Lyons RM, et al. Efficacy of romiplostim in patients with chronic immume thrombocytopenic purpura: a double-blind randomised controlled trial. Lancet. 2008; 371:395-403.
3. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Available at: https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for. Accessed December 6, 2023.
4. Per clinical consult with hematologist/oncologist, June 20, 2018.
5. Immune thrombocytopenia (ITP) in adults: Clinical manifestations and diagnosis. UpToDate Website. Available at: www.uptodate.com. Accessed December 6, 2023.

Prior Authorization Guideline

Guideline ID	GL-228487
Guideline Name	Nubeqa (darolutamide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nubeqa (darolutamide)
Non-metastatic castration-resistant prostate cancer Indicated for the treatment of patients with non-metastatic, castration-resistant prostate cancer (NM-CRPC). **Metastatic hormone-sensitive prostate cancer (mHSPC)** Indicated for the treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.

2 . Criteria

Product Name:Nubeqa	
Diagnosis	Castration-resistant prostate cancer (CRPC)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUBEQA	DAROLUTAMIDE TAB 300 MG	21402425000320	Brand

Approval Criteria

1 - Diagnosis of castration-resistant (chemical or surgical) prostate cancer (CRPC)

Product Name:Nubeqa	
Diagnosis	Hormone-sensitive prostate cancer (HSPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUBEQA	DAROLUTAMIDE TAB 300 MG	21402425000320	Brand

Approval Criteria

1 - Diagnosis of hormone-sensitive prostate cancer (HSPC)

Product Name:Nubeqa	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUBEQA	DAROLUTAMIDE TAB 300 MG	21402425000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Nubeqa Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. August 2022.
2. Klotz L, O'Callaghan C, Ding K, et al. Nadir testosterone within first year of androgen-deprivation therapy (ADT) predicts for time to castration-resistant progression: a secondary analysis of the PR-7 trial of intermittent versus continuous ADT. J Clin Oncol 2015;33:1151-56. doi:10.1200/JCO.2014.58.2973.
3. Smith, M., Hussain, M. et al. Darolutamide and Survival in Metastatic, Hormone-Sensitive Prostate Cancer. Available at https://www.nejm.org/doi/10.1056/NEJMoa2119115?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed. Accessed August 13, 2022.

Prior Authorization Guideline

Guideline ID	GL-233242
Guideline Name	Nucala (mepolizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/17/2015
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Nucala (mepolizumab)
Severe Eosinophilic Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. Limitations of Use: Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus. **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** Indicated for the add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids. **Eosinophilic Granulomatosis with Polyangiitis** Indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). **Hypereosinophilic Syndrome** Indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for greater than or equal to 6 months without an identifiable non-hematologic secondary cause.

2 . Criteria

Product Name:Nucala	
Diagnosis	Severe Asthma
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 40 MG/0.4ML	4460405500E520	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand
NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand

Approval Criteria

1 - Diagnosis of severe asthma [1, A]

AND

2 - Asthma is an eosinophilic phenotype as defined by one of the following [1, 3, B]:

- Baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter
- Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [2-4, H]

OR

3.2 Prior asthma-related hospitalization within the past 12 months

AND

4 - One of the following [2-4, D]:

4.1 Both of the following:

4.1.1 Patient is 6 years of age or older but less than 12 years of age

AND

4.1.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1.2.1 Both of the following [4]:

- Medium-dose inhaled corticosteroid (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.1.2.2 One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg])

OR

4.2 Both of the following:

4.2.1 Patient is 12 years of age or older

AND

4.2.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.2.2.1 Both of the following [4]:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.2.2.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg])

AND

5 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name:Nucala	
Diagnosis	Severe Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 40 MG/0.4ML	4460405500E520	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand
NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications) [C]

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name:Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)

AND

2 - Patient is 18 years of age or older

AND

3 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [10, 11]

AND

4 - Used in combination with another agent for CRSwNP [J]

AND

5 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name:Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS; 0-10 scale])

AND

2 - Used in combination with another agent for CRSwNP [J]

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name:Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand

Approval Criteria

1 - Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)

AND

2 - Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy) [F, 7]

AND

3 - Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone) unless there is a contraindication or intolerance to corticosteroid therapy [F, 7]

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Rheumatologist
- Allergist/Immunologist

Product Name:Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increase in remission time)

Product Name:Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand

Approval Criteria

1 - Diagnosis of hypereosinophilic syndrome (HES)

AND

2 - Patient is 12 years of age or older

AND

3 - Patient has been diagnosed for at least 6 months

AND

4 - Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

AND

5 - Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative

AND

6 - Patient has uncontrolled HES defined as both of the following:

- History of 2 or more flares within the past 12 months [I]
- Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter

AND

7 - Trial and failure, contraindication, or intolerance to one of the following:

- Corticosteroid therapy (e.g., prednisone)
- Cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib)

AND

8 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Hematologist

Product Name:Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose)

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [5]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400

Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [5]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	100-200	> 200-400	> 400

Beclometasone dipropionate (pMDI, extrafine particle, HFA)	50-100	> 100-200	> 200
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Budesonide (nebules)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle*, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50		n.a.
Fluticasone propionate (DPI)	50-100	> 100-200	> 200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	> 100-200	> 200
Mometasone furoate (pMDI, standard particle, HFA)	100		200

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. Patients included across the 3 pivotal studies (DREAM, MENSA, and SIRIUS) [2-4] were characterized with clinical features of severe refractory asthma per American Thoracic Society (ATS) criteria [5]. Per the ATS: "Severe asthma is defined as asthma which requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller (and/or systemic corticosteroids) to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy.'' This definition includes patients who

received an adequate trial of these therapies in whom treatment was stopped due to lack of response. In patients greater than 6 years of age, ‘‘Gold Standard/International Guidelines treatment’’ is high dose ICS plus a long-acting beta 2-agonist (LABA), leukotriene modifier or theophylline and/or continuous or near continuous systemic corticosteroids as background therapy."

B. Inclusion criteria was modified from the DREAM study to the MENSA study to be limited to patients with eosinophils greater than or equal to 150 cells/mcL in the peripheral blood at screening or greater than or equal to 300 cells/mcL at some time during the previous year [3].
C. The primary endpoint for the DREAM and MENSA studies was the annual rate of clinically significant asthma exacerbations as a composite of the required use of systemic corticosteroids for at least 3 days, admission, or ED visit. Both studies showed mepolizumab-treated patients experienced a significant improvement in exacerbation rates compared with baseline and compared with placebo. [2, 3]
D. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [6]
E. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [6].
F. Nucala was approved for Eosinophilic Granulomatosis with Polyangiitis (EGPA) based on the results from the pivotal, 52-week, Phase III MIRRA study. MIRRA looked at the efficacy and safety of 300 mg of mepolizumab administered SQ every four weeks versus placebo as add-on therapy to standard of care (corticosteroids plus or minus immunosuppressants) in 136 patients with relapsing and/or refractory EGPA. MIRRA reported statistically significant outcomes with both co-primary endpoints (i.e., accrued time in remission and proportion of patients achieving remission) in favor of the treatment group [7, 8].
G. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [6]
H. Per P&T Committee, February 2019, revised exacerbation requirement to mirror other IL-5 antagonists.
I. Historical flares were defined as a worsening of HES-related clinical symptoms or a blood eosinophil count requiring an escalation in therapy. [1]
J. Other agents used for CRSwNP include intranasal corticosteroids and nasal saline.

5 . References

1. Nucala prescribing information. GlaxoSmithKline LLC. Philadelphia, PA. March 2023.
2. Pavord ID, Korn S, Howarth P, et al. Mepolizumab for severe eosinophilic asthma (DREAM): a multicentre, double-blind, placebo-controlled trial. Lancet. 2012;380: 651-59.
3. Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. N Engl J Med. 2014;371(13):1198-1207.
4. Bel EH, Wenzel SE, Thompson PJ, et al. Oral Glucocorticoid-Sparing Effect of Mepolizumab in Eosinophilic Asthma. N Engl J Med. 2014;371:1189-1197.
5. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2023 update). 2023 www.ginasthma.org. Accessed April 20234
6. Wechsler ME, Akuthota P, Jayne D, et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med. 2017;376(20):1921-1932.
7. GlaxoSmithKline Press Release. GSK achieves approval for Nucala (mepolizumab) for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) for adults in the US. Website. Available from: https://www.gsk.com/en-gb/media/press-releases/gsk-achieves-approval-for-nucala-mepolizumab-for-the-treatment-of-eosinophilic-granulomatosis-with-polyangiitis-egpa-for-adults-in-the-us/. Accessed March 11, 2021.
8. ClinicalTrials.gov Web site. https://clinicaltrials.gov/ct2/show/NCT03085797. Accessed August 15, 2021.
9. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immunol. 2014;113(4):347-85.
10. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. Int Forum Allergy Rhinol. 2016 Feb; Suppl 1:S22-209.

6 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228703
Guideline Name	Nuedexta (dextromethorphan HBr/quinidine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nuedexta (dextromethorphan HBr/quinidine)
Pseudobulbar Affect (PBA) Indicated for the treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of otherwise unrelated neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the underlying emotional state. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury.

2 . Criteria

Product Name:Nuedexta	
Approval Length	3 months [A]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUEDEXTA	DEXTROMETHORPHAN HBR-QUINIDINE SULFATE CAP 20-10 MG	62609902300120	Brand

Approval Criteria

1 - Diagnosis of pseudobulbar affect (PBA)

AND

2 - Patient has one of the following conditions: [3]

- Amyotrophic lateral sclerosis
- Multiple sclerosis
- Alzheimer's disease
- Parkinson's disease
- Stroke
- Traumatic brain injury

AND

3 - There is an absence of a cardiac rhythm disorder documented by a cardiac test (e.g., electrocardiogram)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Psychiatrist

Product Name:Nuedexta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUEDEXTA	DEXTROMETHORPHAN HBR-QUINIDINE SULFATE CAP 20-10 MG	62609902300120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. Patients should be evaluated for Nuedexta benefit after the initial 3 months of treatment. [2]

4 . References

1. Nuedexta Prescribing Information. Otsuka America Pharmaceuticals, Inc. Rockville, MD. December 2022.
2. Per clinical consultation with neurologist, September 8, 2011 and October 23, 2019.
3. Pseudobulbar affect: prevalence and management. Ther Clin Risk Manag. 2013;9:483-9.

Prior Authorization Guideline

Guideline ID	GL-228489
Guideline Name	Nulibry (fosdenopterin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Nulibry (fosdenopterin)
Molybdenum cofactor deficiency (MoCD) Type A Indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.

2 . Criteria

Product Name:Nulibry	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NULIBRY	FOSDENOPTERIN HYDROBROMIDE FOR IV SOLN 9.5 MG	30906430202120	Brand

Approval Criteria

1 - Both of the following:

- Diagnosis of molybdenum cofactor deficiency (MoCD) Type A
- Genetic mutation in the MOCS1 gene

AND

2 - Patient has clinical and/or laboratory signs and symptoms consistent with MOCD Type A (e.g., seizures, limb/axial hypertonia, elevated levels of urinary sulfite/SSC [s-sulfocysteine] or xanthine in blood/urine, low uric acid in blood/urine)

AND

3 - Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders

Product Name:Nulibry	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NULIBRY	FOSDENOPTERIN HYDROBROMIDE FOR IV SOLN 9.5 MG	30906430202120	Brand

Approval Criteria

1 - Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders

AND

2 - Patient continues to benefit from medication

3 . References

1. Nulibry Prescribing Information. Origin Biosciences, Inc. Boston, MA. March 2021.
2. Study of ORGN001 (formerly ALXN1101) in neonates, infants and children with molybdenum cofactor deficiency (MOCD) type A. ClinicalTrials.gov identifier: NCT02629393. Updated February 26, 2021. Accessed April 12, 2021. https://www.clinicaltrials.gov/ct2/show/study/NCT02629393.
3. Per clinical consultation with pediatrician, April 30, 2021.
4. Mechler, K., Mountford, W., Hoffmann, G. et al. Ultra-orphan diseases: a quantitative analysis of the natural history of molybdenum cofactor deficiency. Genet Med 17, 965–970 (2015). https://doi.org/10.1038/gim.2015.12

Prior Authorization Guideline

Guideline ID	GL-233272
Guideline Name	Ocaliva (obeticholic acid)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	5/19/2016
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Ocaliva (obeticholic acid)
Primary Biliary Cholangitis Indicated for the treatment of primary biliary cholangitis (PBC) in adult patients without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2 . Criteria

Product Name:Ocaliva	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCALIVA	OBETICHOLIC ACID TAB 5 MG	52750060000320	Brand
OCALIVA	OBETICHOLIC ACID TAB 10 MG	52750060000330	Brand

Approval Criteria

1 - Patient is currently receiving treatment with Ocaliva [E, 6, 7]

AND

2 - Diagnosis of primary biliary cholangitis (also known as primary biliary cirrhosis)

AND

3 - One of the following:

3.1 Both of the following:

- Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after at least 12 consecutive months of treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) [A,1,4]
- Used in combination with ursodeoxycholic acid (UDCA)

OR

3.2 History of contraindication or intolerance to ursodeoxycholic acid (UDCA) [B,1-3]

AND

4 - Requested drug will not be used in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

AND

6 - Patient does not have evidence of advanced cirrhosis (i.e. cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy) [C,5]

AND

7 - Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia) [C,5]

Product Name:Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCALIVA	OBETICHOLIC ACID TAB 5 MG	52750060000320	Brand
OCALIVA	OBETICHOLIC ACID TAB 10 MG	52750060000330	Brand

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in ALP level from pre-treatment baseline (i.e., prior obeticholic acid therapy) while on therapy

AND

2 - Requested drug will not be used in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar)

AND

3 - Patient does not have evidence of advanced cirrhosis (i.e. cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy) [C,D,1,5]

AND

4 - Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia) [C,D,1,5]

3 . Endnotes

A. The recommended starting dosage of Ocaliva is 5 mg orally once daily for the first 3 months in adult patients without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, who have not achieved an adequate biochemical response to an appropriate dosage of UDCA for at least 1 year (on a stable dosage for at least 3 months) or are intolerant to UDCA. After the first 3 months, for patients who have not achieved an adequate reduction in ALP and/or total bilirubin and who are tolerating Ocaliva, increase to a maximum dosage of 10 mg once daily [1,4].
B. Obeticholic acid (OCA) was also studied as monotherapy in 60 patients with early disease stage PBC, wherein no UDCA use was allowed for at least 3 months before screening in a phase II trial. Additionally, a phase III trial included only 16 (7%) subjects treated with OCA monotherapy. In an analysis of a pooled dataset consisting of Phase 2 and Phase 3 trials, the responder rate for monotherapy at 3 months was 38%, which is similar to the 41% responder rate achieved for the combination therapy (OCA plus UDCA) [1-3].
C. On 5/26/2021, the FDA issued a black box warning restricting the use of Ocaliva in patients having primary biliary cholangitis (PBC) with advanced cirrhosis of the liver because it can cause serious harm. Some PBC patients with cirrhosis who took Ocaliva, especially those with evidence of advanced cirrhosis, developed liver failure, sometimes requiring liver transplant. In the five years since Ocaliva's accelerated approval, FDA identified 25 cases of serious liver injury leading to liver decompensation or liver failure associated with Ocaliva in PBC patients with cirrhosis, both in those without clinical signs of cirrhosis (compensated) or in those with clinical signs of cirrhosis

(decompensated). Many of these PBC patients had advanced cirrhosis before starting Ocaliva [5].

D. Patients should permanently discontinue Ocaliva if they develop laboratory or clinical evidence of hepatic decompensation (e.g., ascites, jaundice, variceal bleeding, hepatic encephalopathy), have compensated cirrhosis and develop evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia), experience clinically significant hepatic adverse reactions, or develop complete biliary obstruction [1].
E. The Gastrointestinal Drugs Advisory Committee met on September 13, 2024, to discuss whether the supplemental new drug application submitted by Intercept Pharmaceuticals was sufficient to fulfill the accelerated approval postmarketing requirements. The review was extended beyond the initial PDUFA date of Oct. 15, 2024, due to concerns of the reliability of the data from the post-marketing study and observational study, which did not demonstrate clinical benefit, as well as inadequate data to demonstrate the safety of Ocaliva [6]. On Nov. 13, 2024, the FDA issued a complete response letter to Intercept denying full approval of Ocaliva for PBC [7].

4 . References

1. Ocaliva Prescribing Information. Intercept Pharmaceuticals, Inc. New York, NY. February 2022.
2. Kowdley KV, Luketic V, Chapman R, et al. A randomized trial of obeticholic acid monotherapy in patients with primary biliary cholangitis. Hepatology. 2018;67(5):1890-902.
3. Nevens F, Andreone P, Mazzella G, et al. A placebo-controlled trial of obeticholic acid in primary biliary cholangitis. The New England Journal of Medicine. 2016;375(7):375:631-43.
4. Lindor K, Bowlus C, Boyer J, Levy C, Mayo M. Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. Hepatology. 2018.
5. FDA Drug Safety Communication: FDA adds Boxed Warning to restrict use of Ocaliva (obeticholic acid) in primary biliary cholangitis (PBC) patients with advanced cirrhosis. Food and Drug Administration Web site. https://www.fda.gov/drugs/drug-safety-and-availability/due-risk-serious-liver-injury-fda-restricts-use-ocaliva-obeticholic-acid-primary-biliary-cholangitis. Accessed September 2, 2021.
6. Food and Drug Administration. September 13, 2024 Meeting of the Gastrointestinal Drugs Advisory Committee- Minutes. FDA. Published September 13, 2024. Updated October 11, 2024. Accessed November 13, 2024. https://www.fda.gov/media/182630/download
7. Kansteiner F. FDA rejects Intercept's ask for Ocaliva full nod in rare liver disease, but accelerated approval remains. FiercePharma. Published Nov. 12, 2024. Accessed Nov. 13, 2024. https://www.fiercepharma.com/pharma/fda-declines-grant-intercepts-ocaliva-full-approval-rare-liver-disease

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-233226
Guideline Name	Octreotide Products - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	1/19/2001
P&T Revision Date:	12/15/2024

1 . Indications

Drug Name: Sandostatin (octreotide acetate)
Acromegaly Indicated to reduce blood levels of growth hormone and IGF-1 (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. **Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing** Indicated for the treatment of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors. Limitations of Use: Improvement in clinical signs and symptoms, or reduction in tumor size or rate of growth, were not shown in clinical trials performed with Sandostatin Injection; these trials were not optimally designed to detect such effects. **Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea** Indicated for the treatment of the profuse watery diarrhea associated with VIP-secreting tumors. Limitations of Use: Improvement in clinical signs and symptoms, or

reduction in tumor size or rate of growth, were not shown in clinical trials performed with Sandostatin Injection; these trials were not optimally designed to detect such effects.

Drug Name: Sandostatin LAR Depot (octreotide acetate)

General Indicated in patients in whom initial treatment with Sandostatin Injection has been shown to be effective and tolerated.

Acromegaly Indicated for long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal.

Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing Indicated for long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors. Limitation of Use: The effect of Sandostatin LAR on tumor size, rate of growth and development of metastases, has not been determined.

Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea Indicated for long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors. Limitation of Use: The effect of Sandostatin LAR on tumor size, rate of growth and development of metastases, has not been determined.

Drug Name: Mycapssa (octreotide capsule, delayed release)

Acromegaly Indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

2 . Criteria

Product Name:Brand Sandostatin, Generic octreotide, Brand Sandostatin LAR, Generic octreotide LAR	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 50 MCG/ML	3017007010E505	Generic

OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 100 MCG/ML	3017007010E510	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 500 MCG/ML	3017007010E520	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 200 MCG/ML (0.2 MG/ML)	30170070102015	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 1000 MCG/ML (1 MG/ML)	30170070102030	Generic
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 10 MG	30170070106410	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Generic

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery

- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - One of the following:

4.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (applies to Sandostatin LAR and generic octreotide LAR only)

OR

4.2 Trial and failure, or intolerance to generic octreotide (applies to Brand Sandostatin only)

Product Name:Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MYCAPSSA	OCTREOTIDE ACETATE CAP DELAYED RELEASE 20 MG	30170070106520	Brand

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Patient has responded to and tolerated treatment with generic octreotide or lanreotide

AND

4 - Patient requires long-term maintenance treatment

Product Name:Brand Sandostatin, Generic octreotide, Brand Sandostatin LAR, Generic octreotide LAR, Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 50 MCG/ML	3017007010E505	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 100 MCG/ML	3017007010E510	Generic

OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 500 MCG/ML	3017007010E520	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 200 MCG/ML (0.2 MG/ML)	30170070102015	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 1000 MCG/ML (1 MG/ML)	30170070102030	Generic
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 10 MG	30170070106410	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Brand
MYCAPSSA	OCTREOTIDE ACETATE CAP DELAYED RELEASE 20 MG	30170070106520	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)

Product Name:Brand Sandostatin, Generic octreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 50 MCG/ML	3017007010E505	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 100 MCG/ML	3017007010E510	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 500 MCG/ML	3017007010E520	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 200 MCG/ML (0.2 MG/ML)	30170070102015	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 1000 MCG/ML (1 MG/ML)	30170070102030	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - Both of the following (Applies to Brand Sandostatin only):

4.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic octreotide

AND

4.2 Submission of medical records confirming generic octreotide has not been effective AND valid clinical justification provided explaining how Brand Sandostatin is expected to provide benefit when generic octreotide has not been shown to be effective despite having the same active ingredient

Product Name:Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
MYCAPSSA	OCTREOTIDE ACETATE CAP DELAYED RELEASE 20 MG	30170070106520	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of acromegaly

AND

2 - Submission of medical records (e.g., chart notes) of one of the following to confirm diagnosis of acromegaly:

2.1 Serum GH level greater than 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at the time of diagnosis

OR

2.2 Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at the time of diagnosis

AND

3 - One of the following:

3.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

3.2 Not a candidate for surgical resection or pituitary irradiation

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming patient has responded to and tolerated treatment with generic octreotide or lanreotide

AND

5 - Patient requires long-term maintenance treatment

Product Name:Brand Sandostatin LAR, Generic octreotide LAR	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 10 MG	30170070106410	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure,

contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - All of the following (Applies to Brand Sandostatin LAR only):

4.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy

AND

4.2 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic octreotide LAR

AND

4.3 Submission of medical records confirming generic octreotide LAR has not been effective AND valid clinical justification provided explaining how Brand Sandostatin is expected to provide benefit when generic octreotide LAR has not been shown to be effective despite having the same active ingredient

Product Name:Brand Sandostatin, Generic octreotide,Brand Sandostatin LAR, Generic octreotide LAR	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 50 MCG/ML	3017007010E505	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 100 MCG/ML	3017007010E510	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 500 MCG/ML	3017007010E520	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Generic

SANDOSTATIN	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 200 MCG/ML (0.2 MG/ML)	30170070102015	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 1000 MCG/ML (1 MG/ML)	30170070102030	Generic
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 10 MG	30170070106410	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Generic

Approval Criteria

1 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - One of the following:

2.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (applies to Sandostatin LAR and generic octreotide LAR only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (applies to Brand Sandostatin only)

Product Name:Brand Sandostatin, Generic octreotide, Brand Sandostatin LAR, Generic octreotide LAR	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 50 MCG/ML	3017007010E505	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 100 MCG/ML	3017007010E510	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 500 MCG/ML	3017007010E520	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 200 MCG/ML (0.2 MG/ML)	30170070102015	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 1000 MCG/ML (1 MG/ML)	30170070102030	Generic
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 10 MG	30170070106410	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Generic

Approval Criteria

1 - Documentation of an improvement in the number of diarrhea or flushing episodes

Product Name:Brand Sandostatin	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Brand
SANDOSTATIN	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Brand
SANDOSTATIN	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - Both of the following:

2.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic octreotide

AND

2.2 Submission of medical records confirming generic octreotide has not been effective AND valid clinical justification provided explaining how Brand Sandostatin is expected to provide benefit when generic octreotide has not been shown to be effective despite having the same active ingredient

Product Name:Brand Sandostatin LAR, Generic octreotide LAR

Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 50 MCG/ML	3017007010E505	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 100 MCG/ML	3017007010E510	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 500 MCG/ML	3017007010E520	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 200 MCG/ML (0.2 MG/ML)	30170070102015	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 1000 MCG/ML (1 MG/ML)	30170070102030	Generic
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 10 MG	30170070106410	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Brand
MYCAPSSA	OCTREOTIDE ACETATE CAP DELAYED RELEASE 20 MG	30170070106520	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy

Product Name:Brand Sandostatin, Generic octreotide, Brand Sandostatin LAR, Generic octreotide LAR	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 50 MCG/ML	3017007010E505	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 100 MCG/ML	3017007010E510	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 500 MCG/ML	3017007010E520	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 200 MCG/ML (0.2 MG/ML)	30170070102015	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 1000 MCG/ML (1 MG/ML)	30170070102030	Generic

SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 10 MG	30170070106410	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Generic

Approval Criteria

1 - Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - One of the following:

2.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin)

Product Name:Brand Sandostatin, Generic octreotide, Brand Sandostatin LAR, Generic Sandostatin LAR	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 50 MCG/ML	3017007010E505	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 100 MCG/ML	3017007010E510	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 500 MCG/ML	3017007010E520	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 200 MCG/ML (0.2 MG/ML)	30170070102015	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 1000 MCG/ML (1 MG/ML)	30170070102030	Generic
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 10 MG	30170070106410	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response as evidenced by an improvement in the number of diarrhea episodes

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 50 MCG/ML	3017007010E505	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 100 MCG/ML	3017007010E510	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE SUBCUTANEOUS SOLN PREF SYR 500 MCG/ML	3017007010E520	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 50 MCG/ML (0.05 MG/ML)	30170070102005	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 100 MCG/ML (0.1 MG/ML)	30170070102010	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 200 MCG/ML (0.2 MG/ML)	30170070102015	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Generic
SANDOSTATIN	OCTREOTIDE ACETATE INJ 500 MCG/ML (0.5 MG/ML)	30170070102020	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE INJ 1000 MCG/ML (1 MG/ML)	30170070102030	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - Both of the following (Applies to Brand Sandostatin only):

2.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic octreotide

AND

2.2 Submission of medical records confirming generic octreotide has not been effective AND valid clinical justification provided explaining how Brand Sandostatin is expected to provide benefit when generic octreotide has not been shown to be effective despite having the same active ingredient

Product Name:Brand Sandostatin LAR, Generic octreotide LAR	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 10 MG	30170070106410	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Brand
SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Brand
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 20 MG	30170070106420	Generic
OCTREOTIDE ACETATE	OCTREOTIDE ACETATE FOR IM INJ KIT 30 MG	30170070106430	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy

3 . References

1. Sandostatin Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. November 2023.
2. Sandostatin LAR Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2023.
3. Octreotide Prescribing Information. Mylan Institutional LLC. Morgantown, WV. November 2022.
4. Mycapssa Prescribing Information. MW Encap Ltd. Scotland, UK. September 2023.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Odomzo (sonidegib)

Prior Authorization Guideline

Guideline ID	GL-228491
Guideline Name	Odomzo (sonidegib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Odomzo (sonidegib)
Locally advanced basal cell carcinoma (BCC) Indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

2 . Criteria

Product Name:Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ODOMZO	SONIDEGIB PHOSPHATE CAP 200 MG (BASE EQUIVALENT)	21370060200120	Brand

Approval Criteria

1 - Diagnosis of locally advanced basal cell carcinoma [2]

AND

2 - One of the following:

- Cancer has recurred following surgery or radiation therapy
- Patient is not a candidate for surgery or radiation therapy

Product Name:Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ODOMZO	SONIDEGIB PHOSPHATE CAP 200 MG (BASE EQUIVALENT)	21370060200120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Verified with consultant that other specialists such as Dermatologists may prescribe sonidegib in addition to Oncologists. [3]

4 . References

1. Odomzo Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. August 2023.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer. v.3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf. Accessed August 7, 2024.
3. Per clinical consult with oncologist, February 24, 2011.

Ogsiveo (nirogacestat)

Prior Authorization Guideline

Guideline ID	GL-228916
Guideline Name	Ogsiveo (nirogacestat)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ogsiveo (nirogacestat)
Desmoid Tumor Indicated for adult patients with progressing desmoid tumors who require systemic treatment.

2 . Criteria

Product Name:Ogsiveo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 50 MG	21532350200320	Brand
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 100 MG	21532350200330	Brand
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 150 MG	21532350200340	Brand

Approval Criteria

1 - Diagnosis of desmoid tumor

AND

2 - Disease is progressive

AND

3 - Patient requires systemic treatment

Product Name:Ogsiveo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 50 MG	21532350200320	Brand
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 100 MG	21532350200330	Brand
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 150 MG	21532350200340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Ogsiveo Prescribing Information. SpringWorks Therapeutics, Inc. Stamford, CT. April 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Ojemda (tovorafenib)

Prior Authorization Guideline

Guideline ID	GL-233332
Guideline Name	Ojemda (tovorafenib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/18/2025
P&T Approval Date:	7/17/2024
P&T Revision Date:	

1 . Indications

Drug Name: Ojemda (tovorafenib)
Pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation Indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

2 . Criteria

Product Name:Ojemda	
Diagnosis	Pediatric low-grade glioma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OJEMDA	TOVORAFENIB TAB 100 MG	21532075000320	Brand
OJEMDA	TOVORAFENIB FOR ORAL SUSP 25 MG/ML	21532075001920	Brand

Approval Criteria

1 - Diagnosis of pediatric low-grade glioma

AND

2 - Disease is relapsed or refractory

AND

3 - Disease has a BRAF fusion or rearrangement, or BRAF V600 mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Patient does not have known or suspected diagnosis of neurofibromatosis type 1 (NF-1)

AND

5 - Patient is 6 months of age or older

AND

6 - Disease has progressed on or after at least one line of prior systemic therapy (e.g., chemotherapy)

Product Name:Ojemda	
Diagnosis	Pediatric low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OJEMDA	TOVORAFENIB TAB 100 MG	21532075000320	Brand
OJEMDA	TOVORAFENIB FOR ORAL SUSP 25 MG/ML	21532075001920	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Ojemda Prescribing Information. Day One Biopharmaceuticals, Inc. Brisbane CA 94005. May 2024.

4 . Revision History

Date	Notes
2/18/2025	Quartz commercial copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-233187
Guideline Name	Ojjaara (momelotinib) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/16/2023
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Ojjaara (momelotinib)
Myelofibrosis Indicated for the treatment of intermediate or high risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

2 . Criteria

Product Name:Ojjaara	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OJJAARA	MOMELOTINIB DIHYDROCHLORIDE TAB 100 MG	21537540300320	Brand
OJJAARA	MOMELOTINIB DIHYDROCHLORIDE TAB 150 MG	21537540300330	Brand
OJJAARA	MOMELOTINIB DIHYDROCHLORIDE TAB 200 MG	21537540300340	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

2 - Disease is intermediate or high risk

AND

3 - Patient has anemia

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Platelet count is greater than or equal to 50 x 10^9/L

AND

4.1.2 One of the following:

4.1.2.1 Trial and failure, contraindication, or intolerance to Jakafi (ruxolitinib)

OR

4.1.2.2 For continuation of prior therapy

OR

4.2 Platelet count is less than 50 x 10^9/L

Product Name:Ojjaara	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OJJAARA	MOMELOTINIB DIHYDROCHLORIDE TAB 100 MG	21537540300320	Brand
OJJAARA	MOMELOTINIB DIHYDROCHLORIDE TAB 150 MG	21537540300330	Brand
OJJAARA	MOMELOTINIB DIHYDROCHLORIDE TAB 200 MG	21537540300340	Brand

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., symptom improvement, spleen volume reduction)

Product Name:Ojjaara	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OJJAARA	MOMELOTINIB DIHYDROCHLORIDE TAB 100 MG	21537540300320	Brand
OJJAARA	MOMELOTINIB DIHYDROCHLORIDE TAB 150 MG	21537540300330	Brand
OJJAARA	MOMELOTINIB DIHYDROCHLORIDE TAB 200 MG	21537540300340	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of one of the following:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

2 - Disease is intermediate or high risk

AND

3 - Patient has anemia

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Submission of medical records (e.g., chart notes) confirming the platelet count is greater than or equal to 50 x 10^9/L

AND

4.1.2 One of the following:

4.1.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Jakafi (ruxolitinib)

OR

4.1.2.2 For continuation of prior therapy

OR

4.2 Submission of medical records (e.g., chart notes) confirming the platelet count is less than 50 x 10^9/L

3 . References

Ojjaara Prescribing Information. GlaxoSmithKline. Durham, NC. September 2023.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228615
Guideline Name	Olumiant (baricitinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Olumiant (baricitinib)
Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers. Limitation of Use: Not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine. **Coronavirus Disease 2019 (COVID-19)** Indicated for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). **Alopecia Areata (AA)** Indicated for the treatment of adult patients with severe alopecia areata. Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

2 . Criteria

Product Name:Olumiant	
Diagnosis	Rheumatoid Arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OLUMIANT	BARICITINIB TAB 2 MG	66603010000320	Brand
OLUMIANT	BARICITINIB TAB 1 MG	66603010000310	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

methotrexate

leflunomide

sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - One of the following:

5.1 All of the following:

5.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product

Rinvoq (upadacitinib)

Simponi (golimumab)

Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

5.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

Actemra (tocilizumab)

Orencia (abatacept)

OR

5.2 For continuation of prior Olumiant therapy, defined as no more than a 45-day gap in therapy

AND

6 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)^

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. ** For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products ^ Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Olumiant	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OLUMIANT	BARICITINIB TAB 2 MG	66603010000320	Brand
OLUMIANT	BARICITINIB TAB 1 MG	66603010000310	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)^

Notes	^ Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Olumiant	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization, Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OLUMIANT	BARICITINIB TAB 1 MG	66603010000310	Brand
OLUMIANT	BARICITINIB TAB 2 MG	66603010000320	Brand
OLUMIANT	BARICITINIB TAB 4 MG	66603010000340	Brand

Approval Criteria

1 - Diagnosis of COVID-19

AND

2 - Patient is hospitalized

AND

3 - Patient requires one of the following:

Supplemental oxygen

Non-invasive mechanical ventilation

Invasive mechanical ventilation

Extracorporeal membrane oxygenation (ECMO)

Product Name:Olumiant	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OLUMIANT	BARICITINIB TAB 1 MG	66603010000310	Brand
OLUMIANT	BARICITINIB TAB 2 MG	66603010000320	Brand
OLUMIANT	BARICITINIB TAB 4 MG	66603010000340	Brand

Approval Criteria

1 - Diagnosis of alopecia areata

AND

2 - Patient has at least 50% scalp hair loss [1, 4]

AND

3 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, trichotillomania, other scalp disease) [4]

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or potent immunosuppressants (e.g., azathioprine)*

Notes	*Olumiant may be used with concomitant methotrexate, topical or inha led corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Olumiant

Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OLUMIANT	BARICITINIB TAB 1 MG	66603010000310	Brand
OLUMIANT	BARICITINIB TAB 2 MG	66603010000320	Brand
OLUMIANT	BARICITINIB TAB 4 MG	66603010000340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Not used in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or potent immunosuppressants (e.g., azathioprine)*

Notes	*Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products Adalimumab-adaz Hyrimoz Hadlima

Adalimumab-fkjp

4 . References

Olumiant Prescribing Information. Eli Lilly and Company. Indianapolis, IN. June 2022.

Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.

Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.

King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. N Engl J Med 2022;386:1687-99.

5 . Revision History

Date	Notes
11/7/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-233255
Guideline Name	Omega-3-Acid Derivatives
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	9/18/2019
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Vascepa (icosapent ethyl)
Severe Hypertriglyceridemia Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg/dL) hypertriglyceridemia. Limitations of Use: The effect of Vascepa on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. **Prevention of Cardiovascular Events** Indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (greater than or equal to 150 mg/dL) and 1) established cardiovascular disease or 2) diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
Drug Name: Generic icosapent ethyl
Severe Hypertriglyceridemia Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg/dL) hypertriglyceridemia.

Limitations of Use: The effect of icosapent ethyl capsules on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

Prevention of Cardiovascular Events [off-label] Indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (greater than or equal to 150 mg/dL) and 1) established cardiovascular disease or 2) diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

Drug Name: Lovaza (omega-3-acid ethyl esters)

Severe Hypertriglyceridemia Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg per dL) hypertriglyceridemia (HTG). Limitations of Use: The effect of Lovaza on the risk for pancreatitis has not been determined. The effect of Lovaza on cardiovascular mortality and morbidity has not been determined.

2 . Criteria

Product Name:Brand Lovaza, Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LOVAZA	OMEGA-3-ACID ETHYL ESTERS CAP 1 GM	39500045200130	Brand
VASCEPA	ICOSAPENT ETHYL CAP 0.5 GM	39500035100110	Brand
VASCEPA	ICOSAPENT ETHYL CAP 1 GM	39500035100120	Brand
ICOSAPENT ETHYL	ICOSAPENT ETHYL CAP 1 GM	39500035100120	Generic
ICOSAPENT ETHYL	ICOSAPENT ETHYL CAP 0.5 GM	39500035100110	Generic

Approval Criteria

1 - Diagnosis of hypertriglyceridemia

AND

2 - Patient has a pre-treatment triglyceride level greater than or equal to 500 mg/dL

AND

3 - Applies to Brand Lovaza ONLY: Trial and failure, contraindication or intolerance to generic omega-3-acid ethyl esters

Product Name:Brand Lovaza, Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LOVAZA	OMEGA-3-ACID ETHYL ESTERS CAP 1 GM	39500045200130	Brand
VASCEPA	ICOSAPENT ETHYL CAP 0.5 GM	39500035100110	Brand
VASCEPA	ICOSAPENT ETHYL CAP 1 GM	39500035100120	Brand
ICOSAPENT ETHYL	ICOSAPENT ETHYL CAP 1 GM	39500035100120	Generic
ICOSAPENT ETHYL	ICOSAPENT ETHYL CAP 0.5 GM	39500035100110	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Applies to Brand Lovaza ONLY: Trial and failure, contraindication or intolerance to generic omega-3-acid ethyl esters

Product Name:Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Prevention of Cardiovascular Events
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VASCEPA	ICOSAPENT ETHYL CAP 0.5 GM	39500035100110	Brand
VASCEPA	ICOSAPENT ETHYL CAP 1 GM	39500035100120	Brand
ICOSAPENT ETHYL	ICOSAPENT ETHYL CAP 1 GM	39500035100120	Generic
ICOSAPENT ETHYL	ICOSAPENT ETHYL CAP 0.5 GM	39500035100110	Generic

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of hypertriglyceridemia

AND

1.2 Patient has a pre-treatment triglyceride level of 150 mg/dL to 499 mg/dL [2,3]

AND

2 - One of the following:

2.1 Patient has established cardiovascular disease (CVD) (e.g., coronary artery disease, cerebrovascular or carotid disease, peripheral artery disease, etc.) [2]

OR

2.2 Both of the following:

2.2.1 Diagnosis of diabetes mellitus [2]

AND

2.2.2 Patient has two or more risk factors for developing cardiovascular disease (see background section for definitions) [2, 4]

AND

3 - Medication will be used as an adjunct to maximally tolerated statin therapy, unless there is a contraindication or intolerance to statin therapy [2]

Product Name:Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Prevention of Cardiovascular Events
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VASCEPA	ICOSAPENT ETHYL CAP 0.5 GM	39500035100110	Brand
VASCEPA	ICOSAPENT ETHYL CAP 1 GM	39500035100120	Brand
ICOSAPENT ETHYL	ICOSAPENT ETHYL CAP 1 GM	39500035100120	Generic
ICOSAPENT ETHYL	ICOSAPENT ETHYL CAP 0.5 GM	39500035100110	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

AND

2 - Medication continues to be used as an adjunct to maximally tolerated statin therapy, unless there is a contraindication or intolerance to statin therapy [2]

3 . Background

Benefit/Coverage/Program Information

REDUCE-IT Trial Inclusion Criteria for Secondary Prevention Risk Category (Established Cardiovascular Disease) [4]

Man or woman greater than or equal to 45 years of age with one or more of the following:

1. Documented **coronary artery disease** (CAD):

Documented multi vessel CAD (greater than or equal to 50% stenosis in at least two major epicardial coronary arteries – with or without antecedent revascularization);

Documented prior MI; or

Hospitalization for high-risk non-ST-segment elevation acute coronary syndrome (NSTE-ACS) (with objective evidence of ischemia: ST-segment deviation or biomarker positivity).

2. Documented **cerebrovascular or carotid disease**:

Documented prior ischemic stroke;

Symptomatic carotid artery disease with greater than or equal to 50% carotid arterial stenosis;

Asymptomatic carotid artery disease with greater than or equal to 70% carotid arterial stenosis per angiography or duplex ultrasound; or

History of carotid revascularization (catheter-based or surgical).

3. Documented **peripheral arterial disease** (PAD):

Ankle-brachial index (ABI) less than 0.9 with symptoms of intermittent claudication; or

History of aorto-iliac or peripheral arterial intervention (catheter-based or surgical).

REDUCE-IT Trial definition of risk factors for cardiovascular disease

Men greater than or equal to 55 years and women greater than or equal to 65 years
Cigarette smoker or stopped smoking within the past 3 months
Hypertension (pretreatment blood pressure greater than or equal to 140 mmHg systolic or greater than or equal to 90 mmHg diastolic)
HDL-C less than or equal to 40 mg/dL for men or less than or equal to 50 mg/dL for women
High-sensitivity C-reactive protein greater than 3.0 mg/L
Creatinine clearance greater than 30 and less than 60 mL/min
Retinopathy
Micro- or macro-albuminuria

Definition of maximally tolerated statin therapy

HIGH-INTENSITY statin therapy (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) or is unable to tolerage

OR

If unable to tolerate HIGH-INTENSITY statin, then MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] or unable to tolerate

OR

If unable to tolerate MODERATE-INTENSITY statin, then LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg]

OR

Unable to tolerate low- or moderate-, and high-intensity statins because of contraindications; intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: Myalgia (muscle symptoms without CK elevations) or Myositis (muscle symptoms with CK elevations less than 10 times

ULN); or rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [A, 3]

4 . Endnotes

In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [3]

5 . References

Lovaza prescribing information. GlaxoSmithKline. Research Triangle Park, NC. February 2021.

Vascepa prescribing information. Amarin Pharma Inc. Bedminster, NJ. April 2023.

Icosapent ethyl prescribing information. Teva Pharmaceuticals. Parsippany, NJ. August 2021.

Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.

Supplement to: Bhatt DL, Steg PG, Miller M, et al. Cardiovascular risk reduction with icosapent ethyl for hypertriglyceridemia. N Engl J Med 2019;380:11-22. DOI: 10.1056/NEJMoa1812792

6 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Omvoh (mirikizumab-mrkz)

Prior Authorization Guideline

Guideline ID	GL-228619
Guideline Name	Omvoh (mirikizumab-mrkz)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Omvoh (mirikizumab-mrkz) IV & SC
Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adults.

2 . Criteria

Product Name:Omvoh IV	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OMVOH	MIRIKIZUMAB-MRKZ IV SOLN 300 MG/15ML (20 MG/ML)	52504050402030	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [2, 3]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein)

Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [2, 3]:

6-mercaptopurine

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

Azathioprine

Corticosteroids (e.g., prednisone)

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*:

One formulary adalimumab product

Simponi (golimumab)

Skyrizi (risankizumab-rzaa)

Stelara (ustekinumab)

Rinvoq (upadacitinib)

Xeljanz/XR (tofacitinib/ER)

OR

5.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

6 - Will be administered as an intravenous induction dose

Notes	* Includes attestation that the patient has failed to respond to the TNF inhibitor mechanism of action in the past and should not be made to tr y a second TNF inhibitor. In this case, only a single step through a pre ferred agent is required. ** For review process only: Refer to the table in the Background sectio n for carrier-specific formulary adalimumab products

Product Name:Omvoh SC	
Diagnosis	Ulcerative Colitis (UC)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OMVOH	MIRIKIZUMAB-MRKZ SUBCUTANEOUS SOLN AUTO-INJECTOR 100 MG/ML	5250405040D520	Brand
OMVOH	MIRIKIZUMAB-MRKZ SUBCUTANEOUS SOL PREFILL SYRINGE 100 MG/ML	5250405040E520	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name:Omvoh SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OMVOH	MIRIKIZUMAB-MRKZ SUBCUTANEOUS SOLN AUTO-INJECTOR 100 MG/ML	5250405040D520	Brand
OMVOH	MIRIKIZUMAB-MRKZ SUBCUTANEOUS SOL PREFILL SYRINGE 100 MG/ML	5250405040E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products Adalimumab-adaz Hyrimoz Hadlima Adalimumab-fkjp

4 . References

Omvoh prescribing information. Eli Lilly & Co. Indianapolis, IN. April 2024.

Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.

Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

5 . Revision History

Date	Notes
11/7/2024	New program

Prior Authorization Guideline

Guideline ID	GL-233376
Guideline Name	Oncology Injectable
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	12/19/2018
P&T Revision Date:	2/20/2025

1 . Criteria

Product Name:Adcetris, Aliqopa, Arzerra, Bavencio, Beleodaq, Besponsa, Bizengri, Blincyto, Columvi, Cyramza, Danyelza, Elahere, Elrexfio, Elzonris, Empliciti, Enhertu, Epkinly, Erbitux, Eribulin mesylate, Firmagon, Folotyn, Fyarro, Brand Pralatrexate, Halaven, Imfinzi, Imjudo, Istodax, Romidepsin, Jemperli, Kadcyla, Keytruda, Kyprolis, Libtayo, Lumoxiti, Lunsumio, Margenza, Monjuvi, Mylotarg, Opdivo, Opdivo Qvantig, Padcev, Perjeta, Phesgo, Polivy, Portrazza, Poteligeo, Provenge, Rylaze, Sarclisa, Tecentriq, Tecentriq Hybreza, Tecvayli, Tivdak, Vyloy, Yervoy, Zaltrap, Zepzelca	
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

ELZONRIS	TAGRAXOFUSP-ERZS IV SOLN 1000 MCG/ML	21703080302020	Brand
CYRAMZA	RAMUCIRUMAB IV SOLN 100 MG/10ML (FOR INFUSION)	21335070002020	Brand
CYRAMZA	RAMUCIRUMAB IV SOLN 500 MG/50ML (FOR INFUSION)	21335070002040	Brand
KEYTRUDA	PEMBROLIZUMAB IV SOLN 100 MG/4ML (25 MG/ML)	21357953002030	Brand
OPDIVO	NIVOLUMAB IV SOLN 40 MG/4ML	21357941002020	Brand
OPDIVO	NIVOLUMAB IV SOLN 100 MG/10ML	21357941002030	Brand
OPDIVO	NIVOLUMAB IV SOLN 240 MG/24ML	21357941002050	Brand
YERVOY	IPILIMUMAB SOLN FOR IV INFUSION 50 MG/10ML (5 MG/ML)	21355232002020	Brand
YERVOY	IPILIMUMAB SOLN FOR IV INFUSION 200 MG/40ML (5 MG/ML)	21355232002040	Brand
PORTRAZZA	NECITUMUMAB IV SOLN 800 MG/50ML (16 MG/ML)	21360054002020	Brand
TECENTRIQ	ATEZOLIZUMAB IV SOLN 840 MG/14ML	21358215002015	Brand
TECENTRIQ	ATEZOLIZUMAB IV SOLN 1200 MG/20ML	21358215002020	Brand
ADCETRIS	BRENTUXIMAB VEDOTIN FOR IV SOLN 50 MG	21353220202120	Brand
OPDIVO	NIVOLUMAB IV SOLN 120 MG/12ML	21357941002033	Brand
ERBITUX	CETUXIMAB IV SOLN 100 MG/50ML (2 MG/ML)	21360015002020	Brand
ERBITUX	CETUXIMAB IV SOLN 200 MG/100ML (2 MG/ML)	21360015002025	Brand
RYLAZE	ASPARAGINASE ERWINIA CHRYS (RECOMB)-RYWN IM SOLN 10 MG/0.5ML	21250010602020	Brand
ALIQOPA	COPANLISIB HCL FOR IV SOLN 60 MG (BASE EQUIVALENT)	21538020102120	Brand
BLINCYTO	BLINATUMOMAB FOR IV INFUSION 35 MCG	21352020002120	Brand
ARZERRA	OFATUMUMAB CONC FOR IV INFUSION 100 MG/5ML	21351845001320	Brand
ARZERRA	OFATUMUMAB CONC FOR IV INFUSION 1000 MG/50ML	21351845001360	Brand
MARGENZA	MARGETUXIMAB-CMKB IV SOLN 250 MG/10ML (25 MG/ML)	21170034202020	Brand
PADCEV	ENFORTUMAB VEDOTIN-EJFV FOR IV SOLN 20 MG	21357026202120	Brand
PADCEV	ENFORTUMAB VEDOTIN-EJFV FOR IV SOLN 30 MG	21357026202130	Brand
POLIVY	POLATUZUMAB VEDOTIN-PIIQ FOR IV SOLUTION 30 MG	21354860302110	Brand
POLIVY	POLATUZUMAB VEDOTIN-PIIQ FOR IV SOLUTION 140 MG	21354860302120	Brand

PRALATREXATE	PRALATREXATE IV INJ 20 MG/ML	21300054002020	Generic
FOLOTYN	PRALATREXATE IV INJ 20 MG/ML	21300054002020	Generic
PRALATREXATE	PRALATREXATE IV INJ 40 MG/2ML	21300054002025	Generic
FOLOTYN	PRALATREXATE IV INJ 40 MG/2ML	21300054002025	Generic
ZEPZELCA	LURBINECTEDIN FOR IV SOLN 4 MG	21100024002120	Brand
PHESGO	PERTUZUMAB-TRASTUZ-HYALURON-ZZXF INJ 60 MG-60 MG-2000 UNT/ML	21990003552020	Brand
PHESGO	PERTUZUMAB-TRASTUZ-HYALURON-ZZXF INJ 80 MG-40 MG-2000 UNT/ML	21990003552030	Brand
FIRMAGON	DEGARELIX ACETATE FOR INJ 80 MG (BASE EQUIV)	21405525102120	Brand
FIRMAGON	DEGARELIX ACETATE FOR INJ 120 MG/VIAL (240 MG DOSE)	21405525102131	Brand
POTELIGEO	MOGAMULIZUMAB-KPKC IV SOLN 20 MG/5ML (4 MG/ML)	21351135202020	Brand
JEMPERLI	DOSTARLIMAB-GXLY IV SOLN 500 MG/10ML (50 MG/ML)	21357928302020	Brand
KADCYLA	ADO-TRASTUZUMAB EMTANSINE FOR IV SOLN 100 MG	21355070302120	Brand
KADCYLA	ADO-TRASTUZUMAB EMTANSINE FOR IV SOLN 160 MG	21355070302130	Brand
TIVDAK	TISOTUMAB VEDOTIN-TFTV FOR IV SOLUTION 40 MG	21359280802120	Brand
ELAHERE	MIRVETUXIMAB SORAVTANSINE-GYNX IV SOLN 100 MG/20ML	21355030202030	Brand
DANYELZA	NAXITAMAB-GQGK IV SOLN 40 MG/10ML (4 MG/ML)	21356050302020	Brand
LUNSUMIO	MOSUNETUZUMAB-AXGB IV SOLN 1 MG/ML	21352050102020	Brand
LUNSUMIO	MOSUNETUZUMAB-AXGB IV SOLN 30 MG/30ML (1 MG/ML)	21352050102040	Brand
EMPLICITI	ELOTUZUMAB FOR IV SOLN 300 MG	21359030002120	Brand
EMPLICITI	ELOTUZUMAB FOR IV SOLN 400 MG	21359030002130	Brand
BELEODAQ	BELINOSTAT FOR IV INJ 500 MG	21531520002120	Brand
LUMOXITI	MOXETUMOMAB PASUDOTOX-TDFK FOR IV SOLN 1 MG	21352236502120	Brand
MONJUVI	TAFASITAMAB-CXIX FOR IV SOLN 200 MG	21351467202120	Brand
PERJETA	PERTUZUMAB SOLN FOR IV INFUSION 420 MG/14ML (30 MG/ML)	21170054002020	Brand
PROVENGE	SIPULEUCEL-T IV SUSP 50,000,000 CELLS	21651070001820	Brand
ROMIDEPSIN	ROMIDEPSIN FOR IV INJ 10 MG	21531560002120	Generic

ISTODAX	ROMIDEPSIN FOR IV INJ 10 MG	21531560002120	Brand
BAVENCIO	AVELUMAB SOLN FOR IV INFUSION 200 MG/10ML (20 MG/ML)	21358220002020	Brand
BESPONSA	INOTUZUMAB OZOGAMICIN FOR IV SOLN 0.9 MG	21352640202130	Brand
ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI FOR IV SOLN 100 MG	21355070552120	Brand
ERIBULIN MESYLATE	ERIBULIN MESYLATE INJ 1 MG/2ML (0.5 MG/ML)	21500009202020	Generic
HALAVEN	ERIBULIN MESYLATE INJ 1 MG/2ML (0.5 MG/ML)	21500009202020	Brand
COLUMVI	GLOFITAMAB-GXBM IV SOLN 2.5 MG/2.5ML (1 MG/ML)	21352035002020	Brand
COLUMVI	GLOFITAMAB-GXBM IV SOLN 10 MG/10ML (1 MG/ML)	21352035002040	Brand
EPKINLY	EPCORITAMAB-BYSP SUBCUTANEOUS SOLN 4 MG/0.8ML	21352031202020	Brand
EPKINLY	EPCORITAMAB-BYSP SUBCUTANEOUS SOLN 48 MG/0.8ML	21352031202040	Brand
IMFINZI	DURVALUMAB SOLN FOR IV INFUSION 120 MG/2.4ML (50 MG/ML)	21358229002020	Brand
IMFINZI	DURVALUMAB SOLN FOR IV INFUSION 500 MG/10ML (50 MG/ML)	21358229002030	Brand
MYLOTARG	GEMTUZUMAB OZOGAMICIN FOR IV SOLN 4.5 MG	21353630202117	Brand
ELREXFIO	ELRANATAMAB-BCMM SUBCUTANEOUS SOLN 44 MG/1.1ML	21352028152020	Brand
ELREXFIO	ELRANATAMAB-BCMM SUBCUTANEOUS SOLN 76 MG/1.9ML	21352028152040	Brand
TECENTRIQ HYBREZA	ATEZOLIZUMAB-HYALURONIDASE-TQJS INJ 1875-30000 MG-UNIT/15ML	21990002052020	Brand
SARCLISA	ISATUXIMAB-IRFC IV SOLN 100 MG/5ML	21354033202020	Brand
SARCLISA	ISATUXIMAB-IRFC IV SOLN 500 MG/25ML	21354033202030	Brand
IMJUDO	TREMELIMUMAB-ACTL SOLN FOR IV INFUSION 25 MG/1.25ML	21355280102020	Brand
IMJUDO	TREMELIMUMAB-ACTL SOLN FOR IV INFUSION 300 MG/15ML	21355280102040	Brand
TECVAYLI	TECLISTAMAB-CQYV SUBCUTANEOUS SOLN 30 MG/3ML (10 MG/ML)	21352084202020	Brand
TECVAYLI	TECLISTAMAB-CQYV SUBCUTANEOUS SOLN 153 MG/1.7ML (90 MG/ML)	21352084202040	Brand
KYPROLIS	CARFILZOMIB FOR INJ 10 MG	21536025002105	Brand
KYPROLIS	CARFILZOMIB FOR INJ 30 MG	21536025002110	Brand
KYPROLIS	CARFILZOMIB FOR INJ 60 MG	21536025002120	Brand

VYLOY	ZOLBETUXIMAB-CLZB FOR IV SOLN 100 MG	21355190052120	Brand
LIBTAYO	CEMIPLIMAB-RWLC IV SOLN 350 MG/7ML (50 MG/ML)	21357923402030	Brand
ZALTRAP	ZIV-AFLIBERCEPT IV SOLN 100 MG/4ML (FOR INFUSION)	21335010102020	Brand
ZALTRAP	ZIV-AFLIBERCEPT IV SOLN 200 MG/8ML (FOR INFUSION)	21335010102030	Brand
FYARRO	SIROLIMUS PROTEIN-BOUND PARTICLES FOR IV SUSP 100 MG	21532560201920	Brand
BIZENGRI	ZENOCUTUZUMAB-ZBCO IV SOLN PACK 375 MG/18.75ML (750 MG DOSE)	2135979201C520	Brand
OPDIVO QVANTIG	NIVOLUMAB-HYALURONIDASE-NVHY INJ 600-10000 MG-UNIT/5ML	21990002502020	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Prescribed medication is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

Product Name:Abecma, Aucatzyl, Breyanzi, Carvykti, Kymriah, Tecartus, Yescarta	
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
ABECMA	IDECABTAGENE VICLEUCEL IV SUSP 460,000,000 CELLS	21651035401820	Brand
BREYANZI	LISOCABTAGENE MARALEUCEL IV SUSP 70,000,000 CELLS/ML	21651050401820	Brand
CARVYKTI	CILTACABTAGENE AUTOLEUCEL IV SUSP 100,000,000 CELLS	21651025101820	Brand
KYMRIAH	TISAGENLECLEUCEL IV SUSP 250,000,000 CELLS	21651075001820	Brand
KYMRIAH	TISAGENLECLEUCEL IV SUSP 600,000,000 CELLS	21651075001830	Brand
TECARTUS	BREXUCABTAGENE AUTOLEUCEL IV SUSP 100,000,000 CELLS	21651020101810	Brand
TECARTUS	BREXUCABTAGENE AUTOLEUCEL IV SUSP 200,000,000 CELLS	21651020101820	Brand
YESCARTA	AXICABTAGENE CILOLEUCEL IV SUSP 200,000,000 CELLS	21651010101820	Brand
AUCATZYL	OBECABTAGENE AUTOLEUCEL IV SUSP 410,000,000 CELLS	21651062001840	Brand

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Prescribed medication is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

AND

1.1.3 Patient has not previously received CAR-T Cell Therapy for the requested indication

OR

1.2 Meets the off-label administrative guideline criteria

2 . Revision History

Date	Notes
3/13/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-233394
Guideline Name	Onfi (clobazam), Sympazan (clobazam)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Onfi (clobazam) tablets and oral suspension, Sympazan (clobazam) oral film
Lennox-Gastaut syndrome (LGS) Indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older. **Off Label Uses: Refractory Seizures** There is some clinical evidence to support the use in refractory seizures.

2 . Criteria

Product Name:Generic clobazam

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CLOBAZAM	CLOBAZAM TAB 10 MG	72100007000310	Generic
CLOBAZAM	CLOBAZAM TAB 20 MG	72100007000320	Generic
CLOBAZAM	CLOBAZAM SUSPENSION 2.5 MG/ML	72100007001830	Generic

Approval Criteria

1 - All of the following:

1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

1.2 Used as adjunctive therapy [A]

AND

1.3 Patient is 2 years of age or older

AND

1.4 Prescribed by or in consultation with a neurologist

OR

2 - All of the following: [4]

2.1 Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2.2 Used in combination with Diacomit (stiripentol)

AND

2.3 Both of the following:

Patient is 6 months of age or older

Patient weighs greater than or equal to 7 kg

AND

2.4 Prescribed by or in consultation with a neurologist

Product Name:Generic clobazam [off label]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CLOBAZAM	CLOBAZAM TAB 10 MG	72100007000310	Generic
CLOBAZAM	CLOBAZAM TAB 20 MG	72100007000320	Generic
CLOBAZAM	CLOBAZAM SUSPENSION 2.5 MG/ML	72100007001830	Generic

Approval Criteria

1 - All of the following: [B, 5-6]

1.1 Diagnosis of refractory seizures (inadequate response to at least two antiepileptic drugs)

AND

1.2 Used as adjunctive therapy

AND

1.3 Prescribed by or in consultation with a neurologist

Product Name:Brand Onfi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ONFI	CLOBAZAM TAB 10 MG	72100007000310	Brand
ONFI	CLOBAZAM TAB 20 MG	72100007000320	Brand
ONFI	CLOBAZAM SUSPENSION 2.5 MG/ML	72100007001830	Brand

Approval Criteria

1 - All of the following:

1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

1.2 Used as adjunctive therapy [A]

AND

1.3 Patient is 2 years of age or older

AND

1.4 Prescribed by or in consultation with a neurologist

AND

1.5 Trial and failure or intolerance to generic clobazam tablets or oral suspension

OR

2 - All of the following: [4]

2.1 Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2.2 Used in combination with Diacomit (stiripentol)

AND

2.3 Both of the following:

Patient is 6 months of age or older

Patient weighs greater than or equal to 7 kg

AND

2.4 Prescribed by or in consultation with a neurologist

AND

2.5 Trial and failure or intolerance to generic clobazam tablets or oral suspension

Product Name:Brand Onfi [off label]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ONFI	CLOBAZAM TAB 10 MG	72100007000310	Brand
ONFI	CLOBAZAM TAB 20 MG	72100007000320	Brand
ONFI	CLOBAZAM SUSPENSION 2.5 MG/ML	72100007001830	Brand

Approval Criteria

1 - All of the following: [B, 5-6]

1.1 Diagnosis of refractory seizures (inadequate response to at least two antiepileptic drugs)

AND

1.2 Used as adjunctive therapy

AND

1.3 Trial and failure or intolerance to generic clobazam tablets or oral suspension

AND

1.4 Prescribed by or in consultation with a neurologist

Product Name:Sympazan	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYMPAZAN	CLOBAZAM ORAL FILM 5 MG	72100007008205	Brand
SYMPAZAN	CLOBAZAM ORAL FILM 10 MG	72100007008210	Brand
SYMPAZAN	CLOBAZAM ORAL FILM 20 MG	72100007008220	Brand

Approval Criteria

1 - All of the following:

1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

1.2 Used as adjunctive therapy [A]

AND

1.3 Patient is 2 years of age or older

AND

1.4 Prescribed by or in consultation with a neurologist

AND

1.5 One of the following:

Trial and failure or intolerance to generic clobazam tablets or oral suspension

For continuation of prior therapy

OR

2 - All of the following: [4]

2.1 Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2.2 Used in combination with Diacomit (stiripentol)

AND

2.3 Both of the following:

Patient is 6 months of age or older

Patient weighs greater than or equal to 7 kg

AND

2.4 Prescribed by or in consultation with a neurologist

AND

2.5 One of the following:

Trial and failure or intolerance to generic clobazam tablets or oral suspension

For continuation of prior therapy

Product Name:Sympazan [off label]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

SYMPAZAN	CLOBAZAM ORAL FILM 5 MG	72100007008205	Brand
SYMPAZAN	CLOBAZAM ORAL FILM 10 MG	72100007008210	Brand
SYMPAZAN	CLOBAZAM ORAL FILM 20 MG	72100007008220	Brand

Approval Criteria

1 - All of the following: [B, 5-6]

1.1 Diagnosis of refractory seizures (inadequate response to at least two antiepileptic drugs)

AND

1.2 Used as adjunctive therapy

AND

1.3 Prescribed by or in consultation with a neurologist

AND

1.4 One of the following:

Trial and failure or intolerance to generic clobazam tablets or oral suspension

For continuation of prior therapy

Product Name:Generic clobazam, Brand Onfi, or Sympazan	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ONFI	CLOBAZAM TAB 10 MG	72100007000310	Brand

ONFI	CLOBAZAM TAB 20 MG	72100007000320	Brand
ONFI	CLOBAZAM SUSPENSION 2.5 MG/ML	72100007001830	Brand
CLOBAZAM	CLOBAZAM TAB 10 MG	72100007000310	Generic
CLOBAZAM	CLOBAZAM TAB 20 MG	72100007000320	Generic
CLOBAZAM	CLOBAZAM SUSPENSION 2.5 MG/ML	72100007001830	Generic
SYMPAZAN	CLOBAZAM ORAL FILM 5 MG	72100007008205	Brand
SYMPAZAN	CLOBAZAM ORAL FILM 10 MG	72100007008210	Brand
SYMPAZAN	CLOBAZAM ORAL FILM 20 MG	72100007008220	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

Clobazam is approved for adjunctive therapy of LGS. In the pivotal trials, study participants were receiving from 1 to 3 concomitant antiepileptic drugs at stable doses for at least 4 weeks [1, 2]

Refractory status epilepticus is when seizures are not controlled after the administration of two antiseizure medications. [5]

4 . References

Onfi Prescribing Information. Lundbeck. Deerfield, IL. March 2024.

Ng Y-T, Conry JA, Drummond R, et al. Randomized, phase III study results of clobazam in Lennox-Gastaut syndrome. Neurology. 2011;77:1473-81.

Sympazan Prescribing Information. Aquestive Therapeutics. Warren, NJ. March 2023.

Diacomit Prescribing Information. Biocodex. Beauvais, France. June 2024.

Drislane, F. UptoDate. Refractory status epilepticus in adults. March 2023. Available at: https://www.uptodate.com/contents/refractory-status-epilepticus-in-adults?search=onfi&source=search_result&selectedTitle=3~17&usage_type=default&display_rank=3. Accessed April 18, 2023.

Epilepsy Foundation. Drug Resistant Epilepsy. Available at: https://www.epilepsy.com/treatment/medicines/drug-resistant-epilepsy. Accessed April 18, 2023.

5 . Revision History

Date	Notes
3/14/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-233379
Guideline Name	Onpattro (patisiran) & Tegsedi (inotersen)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	10/17/2018
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Onpattro (patisiran), Tegsedi (inotersen)
Hereditary transthyretin-mediated amyloidosis Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

2 . Criteria

Product Name:Onpattro or Tegsedi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ONPATTRO	PATISIRAN SODIUM IV SOLN 10 MG/5ML (2 MG/ML) (BASE EQUIV)	62706060102020	Brand
TEGSEDI	INOTERSEN SOD SUBCUTANEOUS PREF SYR 284 MG/1.5ML (BASE EQ)	6270104010E520	Brand

Approval Criteria

1 - Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy

AND

2 - Presence of a transthyretin (TTR) mutation (e.g., V30M) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [1-4]

AND

3 - One of the following [2, 4]:

Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb

Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2

Patient has a baseline neuropathy impairment score (NIS) between 5 and 130 for Onpattro or a baseline neuropathy impairment score (NIS) between 10 and 130 for Tegsedi

AND

4 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy) [2, 4]

AND

5 - Patient has not had a liver transplant

AND

6 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Vyndaqel)

AND

7 - Prescribed by or in consultation with a neurologist

Product Name:Onpattro or Tegsedi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ONPATTRO	PATISIRAN SODIUM IV SOLN 10 MG/5ML (2 MG/ML) (BASE EQUIV)	62706060102020	Brand
TEGSEDI	INOTERSEN SOD SUBCUTANEOUS PREF SYR 284 MG/1.5ML (BASE EQ)	6270104010E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment)

AND

2 - One of the following [2, 4]:

Patient continues to have a polyneuropathy disability (PND) score less than or equal to IIIb

Patient continues to have a familial amyloidotic polyneuropathy (FAP) stage of 1 or 2

Patient continues to have a neuropathy impairment score (NIS) between 5 and 130 for Onpattro or a neuropathy impairment score (NIS) between 10 and 130 for Tegsedi

AND

3 - Patient has not had a liver transplant

AND

4 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Vyndaqel)

3 . References

Onpattro Prescribing Information. Alnylam Pharmaceuticals, Inc. Cambridge, MA. January 2023.

Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. BMC Neurol. 2017;17:181.

Tegsedi Prescribing Information. Akcea Therapeutics, Inc. Boston, MA. June 2022.

Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen treatment for patients with hereditary transthyretin amyloidosis. N Engl J Med. 2018;379(1):22-31.

4 . Revision History

Date	Notes
3/13/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-229144
Guideline Name	Onureg (azacitidine)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/12/2020
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Onureg (azacitidine)
Acute Myeloid Leukemia (AML) Indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

2 . Criteria

Product Name:Onureg	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ONUREG	AZACITIDINE TAB 200 MG	21300003000320	Brand
ONUREG	AZACITIDINE TAB 300 MG	21300003000330	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin, etc.) [2]

AND

3 - Patient has achieved one of the following:

first complete remission (CR)

complete remission with incomplete blood count recovery (CRi)

AND

4 - Patient is not able to complete intensive curative therapy

Product Name:Onureg	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

ONUREG	AZACITIDINE TAB 200 MG	21300003000320	Brand
ONUREG	AZACITIDINE TAB 300 MG	21300003000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Onureg prescribing information. Celgene Corporation. Summt, NJ. October 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. v3.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed September 19, 2024.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228493
Guideline Name	Opdualag (nivolumab and relatlimab-rmbw)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Opdualag (nivolumab and relatlimab-rmbw)
Metastatic Melanoma Indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.

2 . Criteria

Product Name:Opdualag	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OPDUALAG	NIVOLUMAB-RELATLIMAB-RMBW 240-80 MG/20ML	21993502502020	Brand

Approval Criteria

1 - One of the following diagnoses:

Unresectable melanoma

Metastatic melanoma

AND

2 - Both of the following:

Patient is 12 years of age or older

Patient weighs at least 40 kg (88 lbs)

Product Name:Opdualag	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OPDUALAG	NIVOLUMAB-RELATLIMAB-RMBW 240-80 MG/20ML	21993502502020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Opdualag Prescribing Information. Bristol-Myers Squibb. Princeton, NJ. March 2024.

Opfolda (miglustat)

Prior Authorization Guideline

Guideline ID	GL-228496
Guideline Name	Opfolda (miglustat)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Opfolda (miglustat)
Late-Onset Pompe disease Indicated, in combination with Pombiliti, a hydrolytic lysosomal glycogen-specific enzyme, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

2 . Criteria

Product Name:Opfolda	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OPFOLDA	MIGLUSTAT (GAA DEFICIENCY) CAP 65 MG	30907760000120	Brand

Approval Criteria

1 - Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency)

AND

2 - Disease is confirmed by one of the following: [2, 4-5]

Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

Molecular genetic testing confirms mutations in the GAA gene

AND

3 - Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.) [A]

AND

4 - Medication is used in combination with Pombiliti (cipaglucosidase alfa-atga)

AND

5 - Patient weight is greater than or equal to 40 kg

AND

6 - Trial and inadequate response to one of the following:

Lumizyme

Nexviazyme

AND

7 - Opfolda is not substituted with other miglustat products (i.e., Zavesca, Yargesa)

Product Name:Opfolda	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OPFOLDA	MIGLUSTAT (GAA DEFICIENCY) CAP 65 MG	30907760000120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in FVC, improvement in 6-minute walk distance [6MWD])

AND

2 - Medication is used in combination with Pombiliti (cipaglucosidase alfa-atga)

AND

3 - Opfolda is not substituted with other miglustat products (i.e., Zavesca, Yargesa)

3 . Endnotes

Consensus recommendation based on current clinical guidelines indicate that treatment should be started in patients with late onset Pompe disease when they become symptomatic and/or show signs of disease progression [2, 4-5].

4 . References

Opfolda Prescribing Information. Amicus Therapeutics US, LLC. Philadelphia, PA. Sept 2023.

Diaz, C., Diaz-Manera, J. Therapeutic Options for the Management of Pompe Disease: Current Challenges and Clinical Evidence in Therapeutics and Clinical Risk Management. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9759116/. Accessed November 2, 2023.

Cleveland Clinic - Pompe Disease. Available at: https://my.clevelandclinic.org/health/diseases/15808-pompe-disease. Accessed November 2, 2023.

Cupler, E., Berger, K., Leshner, R., et al. Consensus Treatment Recommendations for Late-Onset Pompe Disease. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3534745/. Accessed November 2, 2023.

Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Available at: https://www.orpha.net/data/patho/Cpg/en/PompeLateOnset_ES_en_CPG_ORPHA420429.pdf. Accessed November 2, 2023.

Prior Authorization Guideline

Guideline ID	GL-228497
Guideline Name	Ophthalmic NSAIDs
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: BROMSITE (bromfenac)
Postoperative Inflammation and Prevention of Ocular Pain Indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery.
Drug Name: ILEVRO (nepafenac)
Postoperative inflammation Indicated for the treatment of pain and inflammation associated with cataract surgery.
Drug Name: NEVANAC (nepafenac)
Postoperative inflammation Indicated for the treatment of pain and inflammation associated with cataract surgery.
Drug Name: Prolensa (bromfenac ophthalmic solution)

Postoperative inflammation Indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

2 . Criteria

Product Name:Ilevro, Nevanac	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ILEVRO	NEPAFENAC OPHTH SUSP 0.3%	86805050001840	Brand
NEVANAC	NEPAFENAC OPHTH SUSP 0.1%	86805050001820	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Patient is greater than 10 but less than 18 years of age [A]

OR

2.2 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to one of the following generics:

Diclofenac ophthalmic solution

Flurbiprofen ophthalmic solution

Ketorolac ophthalmic solution

Product Name:Brand Bromsite, Brand Prolensa, Generic bromfenac ophthalmic solution 0.075%, Generic bromfenac ophthalmic solution 0.07%	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
BROMSITE	BROMFENAC SODIUM OPHTH SOLN 0.075% (BASE EQUIVALENT)	86805005102008	Brand
BROMFENAC SODIUM	BROMFENAC SODIUM OPHTH SOLN 0.075% (BASE EQUIVALENT)	86805005102008	Generic
PROLENSA	BROMFENAC SODIUM OPHTH SOLN 0.07% (BASE EQUIVALENT)	86805005102007	Brand
BROMFENAC SODIUM	BROMFENAC SODIUM OPHTH SOLN 0.07% (BASE EQUIVALENT)	86805005102007	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to one of the following generics:

Diclofenac ophthalmic solution

Flurbiprofen ophthalmic solution

Ketorolac ophthalmic solution

3 . Endnotes

Pediatric patients age greater than 10 but less than 18 years of age are allowed to bypass the trial and failure requirement because Ilevro and Nevanac are approved for this pediatric population, but not Bromsite. The safety and efficacy in pediatric patients below the age of 18 years have not been established for Bromsite. [1, 2, 3]

4 . References

Bromsite Prescribing Information. Sun Pharmaceutical Industries, Inc.; Cranbury, NJ. April 2023.

Ilevro Prescribing Information. Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936. April 2023.

Nevanac Prescribing Information. Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936. April 2023.

Bromfenac Opthalmic Solution 0.075% Prescribing Information. Sun Pharmaceutical Industries, Inc.; Cranbury, NJ. February 2024.

Prior Authorization Guideline

Guideline ID	GL-228499
Guideline Name	Ophthalmic Prostaglandins
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xelpros (latanoprost)
Open-angle glaucoma Indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma. **Ocular hypertension** Indicated for the reduction of elevated intraocular pressure (IOP) in patients with ocular hypertension.
Drug Name: Vyzulta (latanoprostene bunod)
Open-angle glaucoma Indicated for the reduction of intraocular pressure in patients with open-angle glaucoma. **Ocular hypertension** Indicated for the reduction of intraocular pressure in patients with ocular hypertension.
Drug Name: lyuzeh (latanoprost ophthalmic solution)

Open-angle glaucoma, Ocular hypertension Indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

2 . Criteria

Product Name:Iyuzeh, Xelpros, Vyzulta	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
XELPROS	LATANOPROST OPHTH EMULSION 0.005%	86330050001620	Brand
VYZULTA	LATANOPROSTENE BUNOD OPHTH SOLN 0.024%	86330052102020	Brand
IYUZEH	LATANOPROST (PF) OPHTH SOLN 0.005%	86330050002025	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 25 days supply), contraindication, or intolerance to all of the following:

Generic latanoprost

Lumigan

Generic travoprost

3 . References

Xelpros Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. February 2021.

Vyzulta Prescribing Information. Bausch & Lomb Incorporated. Bridgewater, NJ. May 2019.

Iyuzeh Prescribing Information. Thea Pharma Inc. Waltham, MA. December 2022.

Prior Authorization Guideline

Guideline ID	GL-229126
Guideline Name	Opioid Quantity Limit Overrides
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/16/2010
P&T Revision Date:	11/21/2024

Note:

Note: The Opioid Quantity Limit Override Administrative Guideline should be used for single opioids that do not have an FDA-maximum dose. For opioids with an FDA-maximum dose, such as APAP-containing opioid products, please refer to the standard Quantity Limit Override Administrative Guideline or the drug-specific guideline, if applicable.

1 . Criteria

Diagnosis	For Malignant Cancer Pain
Approval Length	5 year(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Opioid quantity limit override			

Approval Criteria

1 - In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used:

1.1 Diagnosis of malignant (cancer) pain*

Notes	Authorization will be issued for long-term therapy. *For oral fentanyl products, please refer to the drug-specific quantity li mit override criteria in the “Oral Fentanyl Products” guideline.

Diagnosis	For Non-Malignant Pain
Approval Length	1 year(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Opioid quantity limit override			

Approval Criteria

1 - In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used:

1.1 Prescribed by a pain specialist or by pain management consultation

AND

1.2 The prescriber maintains and provides chart documentation of the patient’s evaluation, including all of the following:

An appropriate patient medical history and physical examination

A description of the nature and intensity of the pain

Documentation of appropriate dose escalation

Documentation of ongoing, periodic review of the course of opioid therapy

An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function)

Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian

2 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-229127
Guideline Name	Opioid Risk Management
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	
P&T Revision Date:	11/21/2024

1 . Criteria

Product Name:Short-Acting Opioids	
Diagnosis	Cancer or end-of-life care
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
CODEINE SULFATE	CODEINE SULFATE TAB 60 MG	65100020200315	Generic

HYDROMORPHONE HCL	HYDROMORPHONE HCL SUPPOS 3 MG	65100035105205	Generic
DILAUDID	HYDROMORPHONE HCL LIQD 1 MG/ML	65100035100920	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL LIQD 1 MG/ML	65100035100920	Generic
DILAUDID	HYDROMORPHONE HCL TAB 2 MG	65100035100310	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL TAB 2 MG	65100035100310	Generic
DILAUDID	HYDROMORPHONE HCL TAB 4 MG	65100035100320	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL TAB 4 MG	65100035100320	Generic
DILAUDID	HYDROMORPHONE HCL TAB 8 MG	65100035100330	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL TAB 8 MG	65100035100330	Generic
MEPERIDINE HCL	MEPERIDINE HCL ORAL SOLN 50 MG/5ML	65100045102060	Generic
MORPHINE SULFATE	MORPHINE SULFATE TAB 15 MG	65100055100310	Generic
MORPHINE SULFATE	MORPHINE SULFATE TAB 30 MG	65100055100315	Generic
MORPHINE SULFATE	MORPHINE SULFATE ORAL SOLN 10 MG/5ML	65100055102065	Generic
MORPHINE SULFATE	MORPHINE SULFATE ORAL SOLN 20 MG/5ML	65100055102070	Generic
MORPHINE SULFATE	MORPHINE SULFATE ORAL SOLN 100 MG/5ML (20 MG/ML)	65100055102090	Generic
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 5 MG	65100055105205	Generic
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 10 MG	65100055105210	Brand
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 20 MG	65100055105215	Generic
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 30 MG	65100055105220	Generic
OXYCODONE HCL	OXYCODONE HCL CAP 5 MG	65100075100110	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 5 MG	65100075100310	Generic

OXYCODONE HCL	OXYCODONE HCL TAB 10 MG	65100075100320	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 20 MG	65100075100330	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 30 MG	65100075100340	Generic
ROXICODONE	OXYCODONE HCL TAB 5 MG	65100075100310	Brand
ROXICODONE	OXYCODONE HCL TAB 15 MG	65100075100325	Brand
ROXICODONE	OXYCODONE HCL TAB 30 MG	65100075100340	Brand
OXAYDO	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A510	Brand
OXAYDO	OXYCODONE HCL TAB ABUSE DETER 7.5 MG	6510007510A520	Brand
OPANA	OXYMORPHONE HCL TAB 5 MG	65100080100305	Brand
OXYMORPHONE HYDROCHLORIDE	OXYMORPHONE HCL TAB 5 MG	65100080100305	Generic
OPANA	OXYMORPHONE HCL TAB 10 MG	65100080100310	Brand
OXYMORPHONE HYDROCHLORIDE	OXYMORPHONE HCL TAB 10 MG	65100080100310	Generic
NUCYNTA	TAPENTADOL HCL TAB 50 MG	65100091100320	Brand
NUCYNTA	TAPENTADOL HCL TAB 75 MG	65100091100330	Brand
NUCYNTA	TAPENTADOL HCL TAB 100 MG	65100091100340	Brand
PENTAZOCINE/NALOXONE HCL	PENTAZOCINE W/ NALOXONE TAB 50-0.5 MG	65200040300310	Generic
ENDOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	65990002200305	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	65990002200305	Generic
PERCOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	65990002200305	Brand
ENDOCET	OXYCODONE W/ ACETAMINOPHEN TAB 5-325 MG	65990002200310	Generic

OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 5-325 MG	65990002200310	Generic
PERCOCET	OXYCODONE W/ ACETAMINOPHEN TAB 5-325 MG	65990002200310	Brand
ENDOCET	OXYCODONE W/ ACETAMINOPHEN TAB 7.5-325 MG	65990002200327	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 7.5-325 MG	65990002200327	Generic
PERCOCET	OXYCODONE W/ ACETAMINOPHEN TAB 7.5-325 MG	65990002200327	Brand
OXYCODONE/IBUPROFEN	OXYCODONE-IBUPROFEN TAB 5-400 MG	65990002260320	Generic
ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE TAB 300-15 MG	65991002050310	Generic
ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
ACETAMINOPHEN/CODEINE #3	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
ACETAMINOPHEN/CODEINE PHOSPHATE	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
CODEINE/ACETAMINOPHEN	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
TYLENOL/CODEINE #3	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Brand
ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Generic
ACETAMINOPHEN/CODEINE PHOSPHATE	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Generic
CODEINE/ACETAMINOPHEN	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Generic
TYLENOL/CODEINE #4	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Brand
ACETAMINOPHEN/CAFFEINE/DIHYDROCODEINE	ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG	65991303050115	Generic
TREZIX	ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG	65991303050115	Generic
HYDROCODONE/IBUPROFEN	HYDROCODONE-IBUPROFEN TAB 7.5-200 MG	65991702500320	Generic

PROMETHAZINE/PHENYLEPHRINE/CODEINE	PROMETHAZINE-PHENYLEPHRINE-CODEINE SYRUP 6.25-5-10 MG/5ML	43995303101210	Generic
HYCET	HYDROCODONE-ACETAMINOPHEN SOLN 7.5-325 MG/15ML	65991702102015	Brand
HYDROCODONE BITARTRATE/ACETAMINOPHEN	HYDROCODONE-ACETAMINOPHEN SOLN 7.5-325 MG/15ML	65991702102015	Generic
ULTRAM	TRAMADOL HCL TAB 50 MG	65100095100320	Brand
TRAMADOL HCL	TRAMADOL HCL TAB 50 MG	65100095100320	Generic
TRAMADOL HYDROCHLORIDE/ACETAMINOPHEN	TRAMADOL-ACETAMINOPHEN TAB 37.5-325 MG	65995002200320	Generic
ULTRACET	TRAMADOL-ACETAMINOPHEN TAB 37.5-325 MG	65995002200320	Brand
BUTORPHANOL TARTRATE	BUTORPHANOL TARTRATE NASAL SOLN 10 MG/ML	65200020102050	Generic
NALOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	65990002200303	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A540	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A560	Brand
OXYCODONE/ASPIRIN	OXYCODONE-ASPIRIN TAB 4.8355-325 MG	65990002220340	Generic
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG	65990002020310	Brand
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG	65990002020310	Brand
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 6.12-325 MG	65990002020320	Brand
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 6.12-325 MG	65990002020320	Brand
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 8.16-325 MG	65990002020330	Brand
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 8.16-325 MG	65990002020330	Brand

TRAMADOL HYDROCHLORIDE	TRAMADOL HCL TAB 100 MG	65100095100340	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	65990002200303	Generic
OXAYDO	OXYCODONE HCL TAB 5 MG	65100075100310	Brand
OXAYDO	OXYCODONE HCL TAB 7.5 MG	65100075100315	Brand
QDOLO	TRAMADOL HCL ORAL SOLN 5 MG/ML	65100095102005	Brand
PROLATE	OXYCODONE W/ ACETAMINOPHEN SOLN 10-300 MG/5ML	65990002202020	Generic
OXYCODONE HYDROCHLORIDE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN SOLN 10-300 MG/5ML	65990002202020	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A530	Brand
HYDROCODONE/ACETAMINOPHEN	HYDROCODONE/ACETAMINOPHEN TAB 10-325MG	65991702100305	Generic
TRAMADOL HYDROCHLORIDE	TRAMADOL HCL TAB 25 MG	65100095100310	Generic
OXYCODONE HYDROCHLORIDE	OXYCODONE HCL CONC 100 MG/5ML (20 MG/ML)	65100075101320	Generic
OXYCODONE HYDROCHLORIDE	OXYCODONE HCL SOLN 5 MG/5ML	65100075102005	Generic
OXYCODONE HYDROCHLORIDE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN SOLN 5-325 MG/5ML	65990002202005	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A530	Generic
OXYCODONE HYDROCHLORIDE	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A530	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 10 MG	6510007510A535	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A540	Generic
OXYCODONE HYDROCHLORIDE	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A540	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A560	Generic
OXYCODONE HYDROCHLORIDE	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A560	Generic

Approval Criteria

1 - Diagnosis of cancer or end of life care

Notes	Note: Patients with a cancer drug in their prescription claims history w ithin the previous 365 days will not be subject to a max daily dose, da y supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction.

Product Name:Short-Acting Opioids	
Diagnosis	Postoperative Pain Management
Approval Length	14 Day(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
CODEINE SULFATE	CODEINE SULFATE TAB 60 MG	65100020200315	Generic
HYDROMORPHONE HCL	HYDROMORPHONE HCL SUPPOS 3 MG	65100035105205	Generic
DILAUDID	HYDROMORPHONE HCL LIQD 1 MG/ML	65100035100920	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL LIQD 1 MG/ML	65100035100920	Generic
DILAUDID	HYDROMORPHONE HCL TAB 2 MG	65100035100310	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL TAB 2 MG	65100035100310	Generic
DILAUDID	HYDROMORPHONE HCL TAB 4 MG	65100035100320	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL TAB 4 MG	65100035100320	Generic
DILAUDID	HYDROMORPHONE HCL TAB 8 MG	65100035100330	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL TAB 8 MG	65100035100330	Generic
MORPHINE SULFATE	MORPHINE SULFATE TAB 15 MG	65100055100310	Generic

MORPHINE SULFATE	MORPHINE SULFATE TAB 30 MG	65100055100315	Generic
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 5 MG	65100055105205	Generic
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 10 MG	65100055105210	Brand
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 20 MG	65100055105215	Generic
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 30 MG	65100055105220	Generic
OXYCODONE HCL	OXYCODONE HCL CAP 5 MG	65100075100110	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 5 MG	65100075100310	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 10 MG	65100075100320	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 20 MG	65100075100330	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 30 MG	65100075100340	Generic
ROXICODONE	OXYCODONE HCL TAB 5 MG	65100075100310	Brand
ROXICODONE	OXYCODONE HCL TAB 15 MG	65100075100325	Brand
ROXICODONE	OXYCODONE HCL TAB 30 MG	65100075100340	Brand
OXAYDO	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A510	Brand
OXAYDO	OXYCODONE HCL TAB ABUSE DETER 7.5 MG	6510007510A520	Brand
OPANA	OXYMORPHONE HCL TAB 5 MG	65100080100305	Brand
OXYMORPHONE HYDROCHLORIDE	OXYMORPHONE HCL TAB 5 MG	65100080100305	Generic
OPANA	OXYMORPHONE HCL TAB 10 MG	65100080100310	Brand
OXYMORPHONE HYDROCHLORIDE	OXYMORPHONE HCL TAB 10 MG	65100080100310	Generic
NUCYNTA	TAPENTADOL HCL TAB 50 MG	65100091100320	Brand
NUCYNTA	TAPENTADOL HCL TAB 75 MG	65100091100330	Brand

NUCYNTA	TAPENTADOL HCL TAB 100 MG	65100091100340	Brand
PENTAZOCINE/NALOXONE HCL	PENTAZOCINE W/ NALOXONE TAB 50-0.5 MG	65200040300310	Generic
ENDOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	65990002200305	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	65990002200305	Generic
PERCOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	65990002200305	Brand
ENDOCET	OXYCODONE W/ ACETAMINOPHEN TAB 5-325 MG	65990002200310	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 5-325 MG	65990002200310	Generic
PERCOCET	OXYCODONE W/ ACETAMINOPHEN TAB 5-325 MG	65990002200310	Brand
ENDOCET	OXYCODONE W/ ACETAMINOPHEN TAB 7.5-325 MG	65990002200327	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 7.5-325 MG	65990002200327	Generic
PERCOCET	OXYCODONE W/ ACETAMINOPHEN TAB 7.5-325 MG	65990002200327	Brand
OXYCODONE/IBUPROFEN	OXYCODONE-IBUPROFEN TAB 5-400 MG	65990002260320	Generic
ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE TAB 300-15 MG	65991002050310	Generic
ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
ACETAMINOPHEN/CODEINE #3	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
ACETAMINOPHEN/CODEINE PHOSPHATE	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
CODEINE/ACETAMINOPHEN	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
TYLENOL/CODEINE #3	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Brand

ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Generic
ACETAMINOPHEN/CODEINE PHOSPHATE	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Generic
CODEINE/ACETAMINOPHEN	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Generic
TYLENOL/CODEINE #4	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Brand
ACETAMINOPHEN/CAFFEINE/DIHYDROCODEINE	ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG	65991303050115	Generic
TREZIX	ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG	65991303050115	Generic
HYDROCODONE/IBUPROFEN	HYDROCODONE-IBUPROFEN TAB 7.5-200 MG	65991702500320	Generic
ULTRAM	TRAMADOL HCL TAB 50 MG	65100095100320	Brand
TRAMADOL HCL	TRAMADOL HCL TAB 50 MG	65100095100320	Generic
TRAMADOL HYDROCHLORIDE/ACETAMINOPHEN	TRAMADOL-ACETAMINOPHEN TAB 37.5-325 MG	65995002200320	Generic
ULTRACET	TRAMADOL-ACETAMINOPHEN TAB 37.5-325 MG	65995002200320	Brand
BUTORPHANOL TARTRATE	BUTORPHANOL TARTRATE NASAL SOLN 10 MG/ML	65200020102050	Generic
NALOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	65990002200303	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A540	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A560	Brand
OXYCODONE/ASPIRIN	OXYCODONE-ASPIRIN TAB 4.8355-325 MG	65990002220340	Generic
TUXARIN ER	CODEINE PHOS-CHLORPHENIRAMINE MALEATE TAB ER 12HR 54.3-8 MG	43995202327430	Brand
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG	65990002020310	Brand

APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG	65990002020310	Brand
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 6.12-325 MG	65990002020320	Brand
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 6.12-325 MG	65990002020320	Brand
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 8.16-325 MG	65990002020330	Brand
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 8.16-325 MG	65990002020330	Brand
TRAMADOL HYDROCHLORIDE	TRAMADOL HCL TAB 100 MG	65100095100340	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	65990002200303	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A530	Brand
PROLATE	OXYCODONE W/ ACETAMINOPHEN SOLN 10-300 MG/5ML	65990002202020	Generic
OXYCODONE HYDROCHLORIDE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN SOLN 10-300 MG/5ML	65990002202020	Generic
HYCET	HYDROCODONE-ACETAMINOPHEN SOLN 7.5-325 MG/15ML	65991702102015	Brand
HYDROCODONE BITARTRATE/ACETAMINOPHEN	HYDROCODONE-ACETAMINOPHEN SOLN 7.5-325 MG/15ML	65991702102015	Generic
HYDROCODONE/ACETAMINOPHEN	HYDROCODONE/ACETAMINOPHEN TAB 10-325MG	65991702100305	Generic
TRAMADOL HYDROCHLORIDE	TRAMADOL HCL TAB 25 MG	65100095100310	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A530	Generic
OXYCODONE HYDROCHLORIDE	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A530	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 10 MG	6510007510A535	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A540	Generic

OXYCODONE HYDROCHLORIDE	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A540	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A560	Generic
OXYCODONE HYDROCHLORIDE	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A560	Generic

Approval Criteria

1 - Medication is being used to treat postoperative pain

AND

2 - Medication is not being prescribed for pain related to a dental procedure

AND

3 - The dose being prescribed is the dose that the patient was stable on prior to discharge

Notes	*Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction.

Product Name:Short-Acting Opioids	
Diagnosis	All Other Diagnoses
Approval Length	6 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
CODEINE SULFATE	CODEINE SULFATE TAB 60 MG	65100020200315	Generic
HYDROMORPHONE HCL	HYDROMORPHONE HCL SUPPOS 3 MG	65100035105205	Generic
DILAUDID	HYDROMORPHONE HCL TAB 2 MG	65100035100310	Brand

HYDROMORPHONE HCL	HYDROMORPHONE HCL TAB 2 MG	65100035100310	Generic
DILAUDID	HYDROMORPHONE HCL TAB 4 MG	65100035100320	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL TAB 4 MG	65100035100320	Generic
DILAUDID	HYDROMORPHONE HCL TAB 8 MG	65100035100330	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL TAB 8 MG	65100035100330	Generic
MEPERIDINE HCL	MEPERIDINE HCL ORAL SOLN 50 MG/5ML	65100045102060	Generic
MORPHINE SULFATE	MORPHINE SULFATE TAB 15 MG	65100055100310	Generic
MORPHINE SULFATE	MORPHINE SULFATE TAB 30 MG	65100055100315	Generic
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 5 MG	65100055105205	Generic
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 10 MG	65100055105210	Brand
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 20 MG	65100055105215	Generic
MORPHINE SULFATE	MORPHINE SULFATE SUPPOS 30 MG	65100055105220	Generic
OXYCODONE HCL	OXYCODONE HCL CAP 5 MG	65100075100110	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 5 MG	65100075100310	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 10 MG	65100075100320	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 20 MG	65100075100330	Generic
OXYCODONE HCL	OXYCODONE HCL TAB 30 MG	65100075100340	Generic
ROXICODONE	OXYCODONE HCL TAB 5 MG	65100075100310	Brand
ROXICODONE	OXYCODONE HCL TAB 15 MG	65100075100325	Brand
ROXICODONE	OXYCODONE HCL TAB 30 MG	65100075100340	Brand
OXYCODONE HCL	OXYCODONE HCL CONC 100 MG/5ML (20 MG/ML)	65100075101320	Generic

OXYCODONE HCL	OXYCODONE HCL SOLN 5 MG/5ML	65100075102005	Generic
OXAYDO	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A510	Brand
OXAYDO	OXYCODONE HCL TAB ABUSE DETER 7.5 MG	6510007510A520	Brand
OPANA	OXYMORPHONE HCL TAB 5 MG	65100080100305	Brand
OXYMORPHONE HYDROCHLORIDE	OXYMORPHONE HCL TAB 5 MG	65100080100305	Generic
OPANA	OXYMORPHONE HCL TAB 10 MG	65100080100310	Brand
OXYMORPHONE HYDROCHLORIDE	OXYMORPHONE HCL TAB 10 MG	65100080100310	Generic
NUCYNTA	TAPENTADOL HCL TAB 50 MG	65100091100320	Brand
NUCYNTA	TAPENTADOL HCL TAB 75 MG	65100091100330	Brand
NUCYNTA	TAPENTADOL HCL TAB 100 MG	65100091100340	Brand
PENTAZOCINE/NALOXONE HCL	PENTAZOCINE W/ NALOXONE TAB 50-0.5 MG	65200040300310	Generic
ENDOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	65990002200305	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	65990002200305	Generic
PERCOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	65990002200305	Brand
ENDOCET	OXYCODONE W/ ACETAMINOPHEN TAB 5-325 MG	65990002200310	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 5-325 MG	65990002200310	Generic
PERCOCET	OXYCODONE W/ ACETAMINOPHEN TAB 5-325 MG	65990002200310	Brand
ENDOCET	OXYCODONE W/ ACETAMINOPHEN TAB 7.5-325 MG	65990002200327	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 7.5-325 MG	65990002200327	Generic

PERCOCET	OXYCODONE W/ ACETAMINOPHEN TAB 7.5-325 MG	65990002200327	Brand
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN SOLN 5-325 MG/5ML	65990002202005	Generic
OXYCODONE/IBUPROFEN	OXYCODONE-IBUPROFEN TAB 5-400 MG	65990002260320	Generic
ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE TAB 300-15 MG	65991002050310	Generic
ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
ACETAMINOPHEN/CODEINE #3	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
ACETAMINOPHEN/CODEINE PHOSPHATE	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
CODEINE/ACETAMINOPHEN	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Generic
TYLENOL/CODEINE #3	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	65991002050315	Brand
ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Generic
ACETAMINOPHEN/CODEINE PHOSPHATE	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Generic
CODEINE/ACETAMINOPHEN	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Generic
TYLENOL/CODEINE #4	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	65991002050320	Brand
ACETAMINOPHEN/CAFFEINE/DIHYDROCODEINE	ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG	65991303050115	Generic
TREZIX	ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG	65991303050115	Generic
ULTRAM	TRAMADOL HCL TAB 50 MG	65100095100320	
TRAMADOL HCL	TRAMADOL HCL TAB 50 MG	65100095100320	
TRAMADOL HYDROCHLORIDE/ACETAMINOPHEN	TRAMADOL-ACETAMINOPHEN TAB 37.5-325 MG	65995002200320	
ULTRACET	TRAMADOL-ACETAMINOPHEN TAB 37.5-325 MG	65995002200320	

BUTORPHANOL TARTRATE	BUTORPHANOL TARTRATE NASAL SOLN 10 MG/ML	65200020102050	
NALOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	65990002200303	
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A540	
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A560	
OXYCODONE/ASPIRIN	OXYCODONE-ASPIRIN TAB 4.8355-325 MG	659900022203	
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG	65990002020310	
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG	65990002020310	Brand
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 6.12-325 MG	65990002020320	
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 6.12-325 MG	65990002020320	
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 8.16-325 MG	65990002020330	
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 8.16-325 MG	65990002020330	
TRAMADOL HYDROCHLORIDE	TRAMADOL HCL TAB 100 MG	65100095100340	
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	65990002200303	
OXAYDO	OXYCODONE HCL TAB 5 MG	65100075100310	
OXAYDO	OXYCODONE HCL TAB 7.5 MG	65100075100315	
QDOLO	TRAMADOL HCL ORAL SOLN 5 MG/ML	65100095102005	
PROLATE	OXYCODONE W/ ACETAMINOPHEN SOLN 10-300 MG/5ML	65990002202020	
OXYCODONE HYDROCHLORIDE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN SOLN 10-300 MG/5ML	65990002202020	

ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A530	
HYDROCODONE/ACETAMINOPHEN	HYDROCODONE/ACETAMINOPHEN TAB 10-325MG	65991702100305	Generic
TRAMADOL HYDROCHLORIDE	TRAMADOL HCL TAB 25 MG	65100095100310	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A530	Generic
OXYCODONE HYDROCHLORIDE	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A530	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 10 MG	6510007510A535	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A540	Generic
OXYCODONE HYDROCHLORIDE	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A540	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A560	Generic
OXYCODONE HYDROCHLORIDE	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A560	Generic

Approval Criteria

1 - Prescriber certifies that there is an active treatment plan that includes but is not limited to a specific treatment objective and the use of other pharmacological and non-pharmacological agents for pain relief as appropriate

AND

2 - Prescriber certifies that there has been an informed consent document signed and an addiction risk assessment has been performed

AND

3 - Prescriber certifies that a written/signed agreement between prescriber and patient addressing issues of prescription management, diversion, and the use of other substances exists

Notes	Note: Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, da

	y supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction. If the prescriber is unable to certify written documentation to meet criteri on (2) and/or (3), written or verbal attestation from the provider may b e accepted confirming that the prescriber (or prescriber's representati ve) has verbally addressed criterion (2) and/or (3) with the patient.

Product Name:Opioid Cough Medications	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYDROMORPHONE HCL	HYDROMORPHONE HCL SUPPOS 3 MG	65100035105205	Generic
DILAUDID	HYDROMORPHONE HCL LIQD 1 MG/ML	65100035100920	Brand
MEPERIDINE HCL	MEPERIDINE HCL ORAL SOLN 50 MG/5ML	65100045102060	Generic
MORPHINE SULFATE	MORPHINE SULFATE TAB 30 MG	65100055100315	Generic
MORPHINE SULFATE	MORPHINE SULFATE ORAL SOLN 10 MG/5ML	65100055102065	Generic
MORPHINE SULFATE	MORPHINE SULFATE ORAL SOLN 20 MG/5ML	65100055102070	Generic
MORPHINE SULFATE	MORPHINE SULFATE ORAL SOLN 100 MG/5ML (20 MG/ML)	65100055102090	Generic
OXYCODONE HCL	OXYCODONE HCL CONC 100 MG/5ML (20 MG/ML)	65100075101320	Generic
OXYCODONE HCL	OXYCODONE HCL SOLN 5 MG/5ML	65100075102005	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN SOLN 5-325 MG/5ML	65990002202005	Generic
TUZISTRA XR	CODEINE POLIST-CHLORPHEN POLISTER SUSP 14.7-2.8 MG/5ML	4399520231G120	Brand
PROMETHAZINE/CODEINE	PROMETHAZINE W/ CODEINE SYRUP 6.25-10 MG/5ML	43995202341210	Generic

HYDROCODONE POLISTIREX/CHLORPHENIRAMINE POLISTIREX	HYDROCOD POLST-CHLORPHEN POLST ER SUSP 10-8 MG/5ML	4399520236G110	Generic
PROMETHAZINE VC/CODEINE	PROMETHAZINE-PHENYLEPHRINE-CODEINE SYRUP 6.25-5-10 MG/5ML	43995303101210	Generic
PROMETHAZINE/PHENYLEPHRINE/CODEINE	PROMETHAZINE-PHENYLEPHRINE-CODEINE SYRUP 6.25-5-10 MG/5ML	43995303101210	Generic
M-END PE	PHENYLEPHRINE-BROMPHEN W/ CODEINE LIQD 3.33-1.33-6.33 MG/5ML	43995303110916	Brand
POLY-TUSSIN AC	PHENYLEPHRINE-BROMPHEN W/ CODEINE LIQUID 10-4-10 MG/5ML	43995303110935	Brand
CAPCOF	PHENYLEPHRINE-CHLORPHEN W/ CODEINE SYRUP 5-2-10 MG/5ML	43995303141220	Generic
PRO-RED AC	PHENYLEPHRINE-DEXCHLORPHENIR-CODEINE SYRUP 5-1-9 MG/5ML	43995303171220	Brand
RYDEX	PSEUDOEPHEDRINE-BROMPHEN-CODEINE LIQ 10-1.33-6.33 MG/5ML	43995303190922	Generic
MAR-COF BP	PSEUDOEPHEDRINE-BROMPHEN-CODEINE LIQD 30-2-7.5 MG/5ML	43995303190940	Brand
NINJACOF-XG	GUAIFENESIN-CODEINE LIQUID 200-8 MG/5ML	43997002280942	Brand
CODITUSSIN AC	GUAIFENESIN-CODEINE LIQUID 200-10 MG/5ML	43997002280945	Brand
MAR-COF CG EXPECTORANT	GUAIFENESIN-CODEINE LIQUID 225-7.5 MG/5ML	43997002280947	Brand
M-CLEAR WC	GUAIFENESIN-CODEINE SOLN 100-6.3 MG/5ML	43997002282017	Generic
RELCOF C	GUAIFENESIN-CODEINE SOLN 100-6.3 MG/5ML	43997002282017	Generic

CHERATUSSIN AC	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
CODEINE/GUAIFENESIN	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
G TUSSIN AC	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
GUAIATUSSIN AC	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
GUAIFENESIN AC	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
GUAIFENESIN/CODEINE	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
VIRTUSSIN A/C	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
HYCET	HYDROCODONE-ACETAMINOPHEN SOLN 7.5-325 MG/15ML	65991702102015	Brand
HYDROCODONE BITARTRATE/ACETAMINOPHEN	HYDROCODONE-ACETAMINOPHEN SOLN 7.5-325 MG/15ML	65991702102015	Generic
LORTUSS EX	PSEUDOEPHEDRINE W/ COD-GG LIQUID 30-10-100 MG/5ML	43997303300922	Brand
CODITUSSIN DAC	PSEUDOEPHEDRINE W/ COD-GG LIQUID 30-10-200 MG/5ML	43997303300938	Brand
ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE SOLN 120-12 MG/5ML	65991002052020	Generic
QDOLO	TRAMADOL HCL ORAL SOLN 5 MG/ML	65100095102005	Brand
PROLATE	OXYCODONE W/ ACETAMINOPHEN SOLN 10-300 MG/5ML	65990002202020	Generic
OXYCODONE HYDROCHLORIDE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN SOLN 10-300 MG/5ML	65990002202020	Generic
HYDROMET	HYDROCODONE BITART-HOMATROPINE	43101010102010	Generic

	METHYLBROM SOLN 5-1.5 MG/5ML		
HYDROCODONE BITARTRATE/HOMATROPINE METHYLBROMIDE	HYDROCODONE BITART-HOMATROPINE METHYLBROM SOLN 5-1.5 MG/5ML	43101010102010	Generic
HYDROCODONE/HOMATROPINE	HYDROCODONE BITART-HOMATROPINE METHYLBROM SOLN 5-1.5 MG/5ML	43101010102010	Generic

Approval Criteria

1 - Patient is 18 years of age or older

Product Name:Opioid Cough Medications*	
Diagnosis	Greater than the maximum dose as specified in the product prescribing information OR compendia for off-label uses (in the absence of a drug-specific guideline)*
Approval Length	60 Day(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
DILAUDID	HYDROMORPHONE HCL LIQD 1 MG/ML	65100035100920	Brand
HYDROMORPHONE HCL	HYDROMORPHONE HCL LIQD 1 MG/ML	65100035100920	Generic
MEPERIDINE HCL	MEPERIDINE HCL ORAL SOLN 50 MG/5ML	65100045102060	Generic
MORPHINE SULFATE	MORPHINE SULFATE ORAL SOLN 10 MG/5ML	65100055102065	Generic
MORPHINE SULFATE	MORPHINE SULFATE ORAL SOLN 20 MG/5ML	65100055102070	Generic
MORPHINE SULFATE	MORPHINE SULFATE ORAL SOLN 100 MG/5ML (20 MG/ML)	65100055102090	Generic

OXYCODONE HCL	OXYCODONE HCL CONC 100 MG/5ML (20 MG/ML)	65100075101320	Generic
OXYCODONE HCL	OXYCODONE HCL SOLN 5 MG/5ML	65100075102005	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN SOLN 5-325 MG/5ML	65990002202005	Generic
TUZISTRA XR	CODEINE POLIST-CHLORPHEN POLISTER SUSP 14.7-2.8 MG/5ML	4399520231G120	Brand
PROMETHAZINE/CODEINE	PROMETHAZINE W/ CODEINE SYRUP 6.25-10 MG/5ML	43995202341210	Generic
PROMETHAZINE VC/CODEINE	PROMETHAZINE-PHENYLEPHRINE-CODEINE SYRUP 6.25-5-10 MG/5ML	43995303101210	Generic
PROMETHAZINE/PHENYLEPHRINE/CODEINE	PROMETHAZINE-PHENYLEPHRINE-CODEINE SYRUP 6.25-5-10 MG/5ML	43995303101210	Generic
M-END PE	PHENYLEPHRINE-BROMPHEN W/ CODEINE LIQD 3.33-1.33-6.33 MG/5ML	43995303110916	Brand
POLY-TUSSIN AC	PHENYLEPHRINE-BROMPHEN W/ CODEINE LIQUID 10-4-10 MG/5ML	43995303110935	Brand
CAPCOF	PHENYLEPHRINE-CHLORPHEN W/ CODEINE SYRUP 5-2-10 MG/5ML	43995303141220	Generic
PRO-RED AC	PHENYLEPHRINE-DEXCHLORPHENIR-CODEINE SYRUP 5-1-9 MG/5ML	43995303171220	Brand
RYDEX	PSEUDOEPHEDRINE-BROMPHEN-CODEINE LIQ 10-1.33-6.33 MG/5ML	43995303190922	Generic
MAR-COF BP	PSEUDOEPHEDRINE-BROMPHEN-CODEINE LIQD 30-2-7.5 MG/5ML	43995303190940	Brand
NINJACOF-XG	GUAIFENESIN-CODEINE LIQUID 200-8 MG/5ML	43997002280942	Brand

CODITUSSIN AC	GUAIFENESIN-CODEINE LIQUID 200-10 MG/5ML	43997002280945	Brand
M-CLEAR WC	GUAIFENESIN-CODEINE SOLN 100-6.3 MG/5ML	43997002282017	Generic
RELCOF C	GUAIFENESIN-CODEINE SOLN 100-6.3 MG/5ML	43997002282017	Generic
CHERATUSSIN AC	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
CODEINE/GUAIFENESIN	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
G TUSSIN AC	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
GUAIATUSSIN AC	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
GUAIFENESIN AC	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
GUAIFENESIN/CODEINE	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
VIRTUSSIN A/C	GUAIFENESIN-CODEINE SOLN 100-10 MG/5ML	43997002282020	Generic
HYCET	HYDROCODONE-ACETAMINOPHEN SOLN 7.5-325 MG/15ML	65991702102015	Brand
HYDROCODONE BITARTRATE/ACETAMINOPHEN	HYDROCODONE-ACETAMINOPHEN SOLN 7.5-325 MG/15ML	65991702102015	Generic
LORTUSS EX	PSEUDOEPHEDRINE W/ COD-GG LIQUID 30-10-100 MG/5ML	43997303300922	Brand
CODITUSSIN DAC	PSEUDOEPHEDRINE W/ COD-GG LIQUID 30-10-200 MG/5ML	43997303300938	Brand
QDOLO	TRAMADOL HCL ORAL SOLN 5 MG/ML	65100095102005	Brand

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

AND

2 - One of the following:

2.1 The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

OR

2.2 If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition

AND

3 - One of the following:**

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of following compendia:

American Hospital Formulary Service Drug Information

Micromedex DRUGDEX System

Notes	*This guideline only applies in the absence of a drug-specific quantity l imit override guideline. No override requests will be permitted for aceta minophen, alone or in combination with other agents, which will excee d a total of 4 grams of acetaminophen per day. **NOTE: Published bio medical literature may be used as evidence to support safety and addi tional efficacy at higher than maximum doses for the diagnosis provide d.

Product Name:Long Acting Opioids: Nucynta ER	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 50 MG	65100091107420	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 100 MG	65100091107430	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 150 MG	65100091107440	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 200 MG	65100091107450	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 250 MG	65100091107460	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of cancer

OR

1.2 Patient is receiving opioids as part of end-of-life care

AND

2 - Trial and failure, contraindication or intolerance to at least two of the following preferred products

Hydromorphone ER

Morphine sulfate ER

Oxymorphone ER

Hysingla ER

Oxycontin

Xtampza ER

Notes	If the member does not meet the medical necessity reauthorization au thorization criteria requirements, a denial should be issued and a maxi mum 30-day authorization may be authorized one time for the request ed drug/strength combination up to the requested quantity and/or MM E for transition to an alternative treatment.

Product Name:Long Acting Opioids: Nucynta ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 50 MG	65100091107420	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 100 MG	65100091107430	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 150 MG	65100091107440	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 200 MG	65100091107450	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 250 MG	65100091107460	Brand

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic

AND

1.1.2 One of the following:

1.1.2.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.1.2.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

1.2 All of the following:

1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine) titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

2 - None of the following:

For use as an as-needed PRN analgesic

For pain that is mild or not expected to persist for an extended period of time

For acute pain

For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - Trial and failure, contraindication or intolerance to at least two of the following preferred products

Hydromorphone ER

Morphine sulfate ER

Oxymorphone ER

Hysingla ER Oxycontin Xtampza ER	
Notes	If the member does not meet the medical necessity reauthorization au thorization criteria requirements, a denial should be issued and a maxi mum 30-day authorization may be authorized one time for the request ed drug/strength combination up to the requested quantity and/or MM E for transition to an alternative treatment.

Product Name:Long Acting Opioids: Nucynta ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 50 MG	65100091107420	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 100 MG	65100091107430	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 150 MG	65100091107440	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 200 MG	65100091107450	Brand
NUCYNTA ER	TAPENTADOL HCL TAB ER 12HR 250 MG	65100091107460	Brand

Approval Criteria

1 - Documentation has been provided addressing ALL of the following

Treatment goals are defined, including estimated duration of treatment

Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention

Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g., Brief Pain Inventory)

Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g., DAST-10)

Rationale for not tapering and discontinuing

Patient has been screened for comorbid mental health

If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP

If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

Total daily morphine equivalent dose

Notes	If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name:Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER, generic hydromorphone ER

Diagnosis	Non-Cancer/End of Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 9 MG	6510007500A310	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 13.5 MG	6510007500A315	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 18 MG	6510007500A320	Brand

XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 27 MG	6510007500A330	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 36 MG	6510007500A340	Brand
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 30 MG	65100055100432	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 30 MG	65100055100432	Brand
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 200 MG	65100055100480	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 200 MG	65100055100480	Brand
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 5 MG	65100080107405	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 7.5 MG	65100080107407	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 10 MG	65100080107410	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 15 MG	65100080107415	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 20 MG	65100080107420	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 30 MG	65100080107430	Generic

OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 40 MG	65100080107440	Generic
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG	6510003010A810	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG	6510003010A820	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG	6510003010A830	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG	6510003010A840	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG	6510003010A850	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG	6510003010A860	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG	6510003010A870	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 10 MG	6510007510A710	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 10 MG	6510007510A710	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 15 MG	6510007510A715	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 15 MG	6510007510A715	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 20 MG	6510007510A720	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 20 MG	6510007510A720	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 30 MG	6510007510A730	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 30 MG	6510007510A730	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 40 MG	6510007510A740	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 40 MG	6510007510A740	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 60 MG	6510007510A760	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 60 MG	6510007510A760	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 80 MG	6510007510A780	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 80 MG	6510007510A780	Brand

MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 30 MG	65100055207020	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 45 MG	65100055207025	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 60 MG	65100055207030	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 75 MG	65100055207035	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 90 MG	65100055207040	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 120 MG	65100055207050	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 8 MG	65100035107521	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 12 MG	65100035107531	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 16 MG	65100035107541	Generic
HYDROMORPHONE HYDROCHLORIDE ER	HYDROMORPHONE HCL TAB ER 24HR 32 MG	65100035107556	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG	6510003010A810	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG	6510003010A820	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG	6510003010A830	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG	6510003010A840	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG	6510003010A850	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG	6510003010A860	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG	6510003010A870	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 10 MG	65100055107010	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 20 MG	65100055107020	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 30 MG	65100055107030	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 50 MG	65100055107040	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 60 MG	65100055107045	Generic

MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 80 MG	65100055107050	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 100 MG	65100055107060	Generic
METHADONE HCL	METHADONE HYDROCHLORIDE	65100050100310	
METHADONE HYDROCHLORIDE	METHADONE HYDROCHLORIDE	65100050100310	
METHADONE HYDROCHLORIDE	METHADONE HYDROCHLORIDE	65100050100305	
FENTANYL	FENTANYL TD PATCH 72HR 12 MCG/HR	65100025008610	Generic
FENTANYL	FENTANFENTANYL TD PATCH 72HR 25 MCG/HRYL TD PATCH 72HR 50 MCG/HR	65100025008620	Generic
FENTANYL	FENTANYL TD PATCH 72HR 50 MCG/HR	65100025008630	Generic
FENTANYL	FENTANYL TD PATCH 72HR 75 MCG/HR	65100025008640	Generic
FENTANYL	FENTANYL TD PATCH 72HR 100 MCG/HR	65100025008650	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 10 MG	65100030106910	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 15 MG	65100030106915	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 20 MG	65100030106920	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 30 MG	65100030106930	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 40 MG	65100030106940	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 50 MG	65100030106950	Generic

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic

AND

1.1.2 One of the following:

1.1.2.1 For patients that are filling the prescribed medication for the first time, prior to the

start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.1.2.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

1.2 All of the following:

1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine) titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

2 - None of the following:

For use as an as-needed PRN analgesic

For pain that is mild or not expected to persist for an extended period of time

For acute pain

For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

Notes	If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not m eet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative trea tment.

Product Name:Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER, generic hydromorphone ER

Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 9 MG	6510007500A310	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 13.5 MG	6510007500A315	Brand

XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 18 MG	6510007500A320	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 27 MG	6510007500A330	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 36 MG	6510007500A340	Brand
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 30 MG	65100055100432	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 30 MG	65100055100432	Brand
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 200 MG	65100055100480	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 200 MG	65100055100480	Brand
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 5 MG	65100080107405	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 7.5 MG	65100080107407	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 10 MG	65100080107410	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 15 MG	65100080107415	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 20 MG	65100080107420	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 30 MG	65100080107430	Generic

OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 40 MG	65100080107440	Generic
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG	6510003010A810	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG	6510003010A820	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG	6510003010A830	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG	6510003010A840	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG	6510003010A850	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG	6510003010A860	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG	6510003010A870	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 10 MG	6510007510A710	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 10 MG	6510007510A710	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 15 MG	6510007510A715	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 15 MG	6510007510A715	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 20 MG	6510007510A720	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 20 MG	6510007510A720	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 30 MG	6510007510A730	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 30 MG	6510007510A730	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 40 MG	6510007510A740	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 40 MG	6510007510A740	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 60 MG	6510007510A760	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 60 MG	6510007510A760	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 80 MG	6510007510A780	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 80 MG	6510007510A780	Brand

MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 30 MG	65100055207020	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 45 MG	65100055207025	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 60 MG	65100055207030	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 75 MG	65100055207035	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 90 MG	65100055207040	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 120 MG	65100055207050	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 8 MG	65100035107521	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 12 MG	65100035107531	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 16 MG	65100035107541	Generic
HYDROMORPHONE HYDROCHLORIDE ER	HYDROMORPHONE HCL TAB ER 24HR 32 MG	65100035107556	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG	6510003010A810	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG	6510003010A820	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG	6510003010A830	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG	6510003010A840	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG	6510003010A850	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG	6510003010A860	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG	6510003010A870	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 10 MG	65100055107010	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 20 MG	65100055107020	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 30 MG	65100055107030	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 50 MG	65100055107040	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 60 MG	65100055107045	Generic

MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 80 MG	65100055107050	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 100 MG	65100055107060	Generic
METHADONE HYDROCHLORIDE	METHADONE HYDROCHLORIDE 10 mg	65100050100310	
METHADONE HYDROCHLORIDE	METHADONE HYDROCHLORIDE 10 mg	65100050100310	
METHADONE HYDROCHLORIDE	METHADONE HYDROCHLORIDE 5 mg	65100050100305	
FENTANYL	FENTANYL TD PATCH 72HR 12 MCG/HR	65100025008610	Generic
FENTANYL	FENTANYL TD PATCH 72HR 25 MCG/HR	65100025008620	Generic
FENTANYL	FENTANYL TD PATCH 72HR 50 MCG/HR	65100025008630	Generic
FENTANYL	FENTANYL TD PATCH 72HR 75 MCG/HR	65100025008640	Generic
FENTANYL	FENTANYL TD PATCH 72HR 100 MCG/HR	65100025008650	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 10 MG	65100030106910	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 15 MG	65100030106915	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 20 MG	65100030106920	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 30 MG	65100030106930	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 40 MG	65100030106940	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 50 MG	65100030106950	Generic

Approval Criteria

1 - Documentation has been provided addressing ALL of the following:

Treatment goals are defined, including estimated duration of treatment

Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention

Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory)

Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10)

Rationale for not tapering and discontinuing opioid

Patient has been screened for comorbid mental health conditions

If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP

If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

Total daily morphine equivalent dose

Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name:Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER, generic hydromorphone ER

Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 9 MG	6510007500A310	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 13.5 MG	6510007500A315	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 18 MG	6510007500A320	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 27 MG	6510007500A330	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 36 MG	6510007500A340	Brand

MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 30 MG	65100055100432	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 30 MG	65100055100432	Brand
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 200 MG	65100055100480	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 200 MG	65100055100480	Brand
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 5 MG	65100080107405	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 7.5 MG	65100080107407	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 10 MG	65100080107410	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 15 MG	65100080107415	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 20 MG	65100080107420	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 30 MG	65100080107430	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 40 MG	65100080107440	Generic
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG	6510003010A810	Brand

HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG	6510003010A820	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG	6510003010A830	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG	6510003010A840	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG	6510003010A850	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG	6510003010A860	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG	6510003010A870	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 10 MG	6510007510A710	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 10 MG	6510007510A710	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 15 MG	6510007510A715	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 15 MG	6510007510A715	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 20 MG	6510007510A720	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 20 MG	6510007510A720	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 30 MG	6510007510A730	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 30 MG	6510007510A730	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 40 MG	6510007510A740	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 40 MG	6510007510A740	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 60 MG	6510007510A760	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 60 MG	6510007510A760	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 80 MG	6510007510A780	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 80 MG	6510007510A780	Brand
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 30 MG	65100055207020	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 45 MG	65100055207025	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 60 MG	65100055207030	Generic

MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 75 MG	65100055207035	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 90 MG	65100055207040	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 120 MG	65100055207050	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 8 MG	65100035107521	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 12 MG	65100035107531	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 16 MG	65100035107541	Generic
HYDROMORPHONE HYDROCHLORIDE ER	HYDROMORPHONE HCL TAB ER 24HR 32 MG	65100035107556	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG	6510003010A810	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG	6510003010A820	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG	6510003010A830	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG	6510003010A840	
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG	6510003010A850	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG	6510003010A860	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG	6510003010A870	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 10 MG	65100055107010	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 20 MG	65100055107020	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 30 MG	65100055107030	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 50 MG	65100055107040	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 60 MG	65100055107045	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 80 MG	65100055107050	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 100 MG	65100055107060	Generic
METHADONE HCL	METHADONE HCL TAB 5 MG	65100050100305	Generic

METHADONE HYDROCHLORIDE	METHADONE HCL TAB 5 MG	65100050100305	Generic
METHADONE HCL	METHADONE HYDROCHLORIDE	65100050100310	Generic
METHADONE HYDROCHLORIDE	METHADONE HYDROCHLORIDE	65100050100310	Generic
FENTANYL	FENTANYL TD PATCH 72HR 25 MCG/HR	65100025008620	
FENTANYL	FENTANYL TD PATCH 72HR 50 MCG/HR	65100025008630	
FENTANYL	FENTANYL TD PATCH 72HR 75 MCG/HR	65100025008640	
FENTANYL	FENTANYL TD PATCH 72HR 100 MCG/HR	65100025008650	
FENTANYL	FENTANYL TD PATCH 72HR 12 MCG/HR	65100025008610	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 10 MG	65100030106910	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 15 MG	65100030106915	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 20 MG	65100030106920	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 30 MG	65100030106930	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 40 MG	65100030106940	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 50 MG	65100030106950	Generic

Approval Criteria

1 - One of the following:

1.1 Diagnosis of cancer

OR

1.2 Patient is receiving opioids as part of end-of-life care

Product Name:Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Brand
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Generic

BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Generic

Approval Criteria

1 - Patient is being treated for cancer related pain or pain associated with end-of-life

Notes	*Prior authorization may not apply depending on the plan

Product Name:Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
Diagnosis	Non- Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Brand
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic

BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Generic

Approval Criteria

1 - The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment

AND

2 - None of the following:

For use as an as-needed PRN analgesic

For pain that is mild or not expected to persist for an extended period of time

For acute pain

For opioid dependence

AND

3 - The patient is not receiving other long-acting opioids concurrently

Notes	*Prior authorization may not apply depending on the plan. If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name:Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
Diagnosis	Non-Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Brand
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic

BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Generic

Approval Criteria

1 - Documentation has been provided addressing ALL of the following

Treatment goals are defined, including estimated duration of treatment

Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention

Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory)

Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10) Rationale for not tapering and discontinuing opioid Patient has been screened for comorbid mental health conditions If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression Total daily morphine equivalent dose	
Notes	*Prior authorization may not apply depending on the plan. If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

2 . References

Zohydro ER Prescribing Information.Currax Pharmaceuticals LLC. October 2019.

3 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228627
Guideline Name	Opzelura (ruxolitinib) - ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Opzelura (ruxolitinib)
Atopic Dermatitis Indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Limitation of Use: Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended. **Nonsegmental Vitiligo** Indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older. Limitation of Use: Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

2 . Criteria

Product Name:Opzelura	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
OPZELURA	RUXOLITINIB PHOSPHATE CREAM 1.5%	90272060503720	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of mild to moderate atopic dermatitis

AND

1.1.2 One of the following:

1.1.2.1 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to one prescription strength topical corticosteroid (see Table 1 in Background section), unless the affected area is sensitive (i.e., face, axillae, groin) [2]

OR

1.1.2.2 Trial and failure (of a minimum 30 day supply) or intolerance to one generic topical calcineurin inhibitor (e.g., tacrolimus ointment), unless the patient is not a candidate for therapy (e.g., immunocompromised) [2]

OR

1.2 Both of the following:

1.2.1 Diagnosis of nonsegmental vitiligo

AND

1.2.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to ONE of the following [3]:

Medium or higher potency topical corticosteroid

Tacrolimus ointment

Product Name:Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OPZELURA	RUXOLITINIB PHOSPHATE CREAM 1.5%	90272060503720	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of mild to moderate atopic dermatitis

AND

2 - Submission of medical records (e.g., chart notes) confirming one of the following:

Greater than or equal to 3% body surface area (BSA) involvement

Involvement of sensitive body areas (e.g., face, hands, feet, scalp, groin)

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

Dermatologist

Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply of non-pharmacologic topical therapies (e.g., moisturizers) [2]

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to ALL of the following [2]:

Medium or higher potency topical corticosteroid

Elidel (pimecrolimus) cream* OR Tacrolimus ointment

Eucrisa (crisaborole) ointment*

AND

7 - Submission of medical records (e.g., chart notes) or absence of paid claims confirming Opzelura is not used in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

AND

8 - Opzelura will only be used for short-term and/or non-continuous chronic treatment

Notes	*Product may require step therapy

Product Name:Opzelura	
Diagnosis	Nonsegmental Vitiligo
Approval Length	6 Months [B]

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OPZELURA	RUXOLITINIB PHOSPHATE CREAM 1.5%	90272060503720	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of nonsegmental vitiligo

AND

2 - Patient is 12 years of age or older

AND

3 - Prescribed by or in consultation with a dermatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following [3, 4]:

Minimum 3-month duration of a medium or higher potency topical corticosteroid

Minimum 6-month duration of tacrolimus ointment

AND

5 - Submission of medical records (e.g., chart notes) or absence of paid claims confirming Opzelura is not used in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

3 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05

	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

Opzelura should be discontinued when signs and symptoms (e.g., itch, rash, and redness) of atopic dermatitis resolve. If signs and symptoms do not improve within 8 weeks, patients should be reexamined by their healthcare provider.

Satisfactory patient response may require treatment with Opzelura for more than 24 weeks. If the patient does not find the repigmentation meaningful by 24 weeks, the patient should be re-evaluated by the healthcare provider.

5 . References

Opzelura Prescribing Information. Incyte Corp. Wilmington, DE. September 2023.

Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.

Taieb A, Alomar A, Bohm M, et al. Guidelines for the management of vitiligo: the European Dermatology Forum consensus. Br J Dermatol. 2013;168(1):5-19.

Drake LA, Dinehart SM, Farmer ER, et al. Guidelines of care for vitiligo. J Am Acad Dermatol. 1996; 35(4):620-6.

6 . Revision History

Date	Notes
11/7/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-228629
Guideline Name	Oral Antidepressants
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Aplenzin (bupropion extended-release)
Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD), as defined by the Diagnostic and Statistical Manual (DSM). **Seasonal Affective Disorder** Indicated for the prevention of seasonal major depressive episodes in patients with a diagnosis of seasonal affective disorder (SAD).
Drug Name: Citalopram capsules
Major Depressive Disorders Indicated for the treatment of major depressive disorder (MDD) in adults.
Drug Name: Desvenlafaxine ER
Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD) in adults.
Drug Name: Fetzima (levomilnacipran extended-release)

Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD).

Drug Name: Forfivo XL (bupropion extended-release)

Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD), as defined by the Diagnostic and Statistical Manual (DSM).

Drug Name: Paxil (paroxetine) oral suspension

Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD).

Obsessive Compulsive Disorder Indicated for the treatment of obsessive compulsive disorder (OCD)

Panic Disorder Indicated for the treatment of panic disorder (PD).

Social Anxiety Disorder Indicated for the treatment of social anxiety disorder (SAD).

Generalized Anxiety Disorder Indicated for the treatment of generalized anxiety disorder (GAD).

Posttraumatic Stress Disorder Indicated for the treatment of posttraumatic stress disorder (PTSD).

Drug Name: Trintellix (vortioxetine)

Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD) in adults.

Drug Name: Sertraline capsules

Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD) in adults.

Obsessive Compulsive Disorder Indicated for the treatment of obsessive compulsive disorder (OCD) in adults and pediatric patients 6 years and older.

Drug Name: Venlafaxine ER

Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD) in adults.

Generalized Anxiety Disorder Indicated for the treatment of generalized anxiety disorder (GAD) in adults.

Drug Name: Auvelity (dextromethorphan hydrobromide and bupropion extended-release)

Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD) in adults.
Drug Name: Drizalma sprinkle (duloxetine delayed-relased capsules)
Multiple Indications Indicated for the treatment of: 1) Major Depressive Disorder in adults. 2) Generalized Anxiety Disorder in adults and pediatric patients 7 years of age and older. 3) Diabetic Peripheral Neuropathy in adults. 4) Fibromyalgia in adults. 5) Chronic Musculoskeletal Pain in adults.

2 . Criteria

Product Name:Aplenzin, Forfivo XL, or Bupropion HCL 450mg ER (XL)	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
APLENZIN	BUPROPION HBR TAB SR 24HR 174 MG	58300040207520	Brand
APLENZIN	BUPROPION HBR TAB SR 24HR 348 MG	58300040207530	Brand
APLENZIN	BUPROPION HBR TAB SR 24HR 522 MG	58300040207540	Brand
FORFIVO XL	BUPROPION HCL TAB ER 24HR 450 MG	58300040107545	Generic
BUPROPION HYDROCHLORIDE ER (XL)	BUPROPION HCL TAB ER 24HR 450 MG	58300040107545	Generic

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30-day supply) or intolerance to a generic bupropion XL product

OR

2 - For continuation of prior therapy

Product Name:Brand Desvenlafaxine ER, Brand Citalopram capsules, Drizalma sprinkle, Paxil suspension, Brand Sertraline capsules, Trintellix, or Brand Venlafaxine ER	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TRINTELLIX	VORTIOXETINE HBR TAB 5 MG (BASE EQUIV)	58120093100310	
TRINTELLIX	VORTIOXETINE HBR TAB 10 MG (BASE EQUIV)	58120093100320	
TRINTELLIX	VORTIOXETINE HBR TAB 20 MG (BASE EQUIV)	58120093100340	
TRINTELLIX			
PAXIL	PAROXETINE HCL ORAL SUSP 10 MG/5ML (BASE EQUIV)	58160060001820	Brand
SERTRALINE HYDROCHLORIDE	SERTRALINE HCL CAP 150 MG	58160070100130	Brand
SERTRALINE HYDROCHLORIDE	SERTRALINE HCL CAP 200 MG	58160070100140	Brand
CITALOPRAM HYDROBROMIDE	CITALOPRAM HYDROBROMIDE CAP 30 MG	58160020100120	Brand
DESVENLAFAXINE ER	DESVENLAFAXINE TAB ER 24HR 50 MG	58180020007520	Brand
DESVENLAFAXINE ER	DESVENLAFAXINE TAB ER 24HR 100 MG	58180020007540	Brand
VENLAFAXINE BESYLATE ER	VENLAFAXINE BESYLATE TAB ER 24HR 112.5 MG	58180090057520	Brand
DRIZALMA SPRINKLE	DULOXETINE HCL CAP DELAYED RELEASE SPRINKLE 20 MG (BASE EQ)	5818002510H120	Brand
DRIZALMA SPRINKLE	DULOXETINE HCL CAP DELAYED RELEASE SPRINKLE 30 MG (BASE EQ)	5818002510H130	Brand
DRIZALMA SPRINKLE	DULOXETINE HCL CAP DELAYED RELEASE SPRINKLE 40 MG (BASE EQ)	5818002510H140	Brand
DRIZALMA SPRINKLE	DULOXETINE HCL CAP DELAYED RELEASE SPRINKLE 60 MG (BASE EQ)	5818002510H160	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to any two of the following generics:

bupropion

citalopram tablets or oral solution

desvenlafaxine succinate extended-release (ER)

duloxetine

escitalopram

fluoxetine

mirtazepine

paroxetine

paroxetine ER

sertraline tablets or oral solution

venlafaxine

venlafaxine ER

OR

2 - For continuation of prior therapy

Product Name:Auvelity	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
AUVELITY	DEXTROMETHORPHAN HBR-BUPROPION HCL TAB ER 45-105 MG	58999902300420	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 One of the following

1.2.1 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to any three of the following generics:

bupropion

citalopram tablets or oral solution

desvenlafaxine succinate extended-release (ER)

duloxetine

escitalopram

fluoxetine

mirtazepine

paroxetine

paroxetine ER

sertraline tablets or oral solution

venlafaxine

venlafaxine ER

OR

1.2.2 Patient has treatment-resistant depression as defined by a failure to respond to a trial of at least 2 antidepressants after at least 4 to 6 weeks of treatment at the maximally tolerated dose [A]

OR

2 - For continuation of prior therapy

Product Name:Fetzima or Fetzima Pack	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
FETZIMA	LEVOMILNACIPRAN HCL CAP SR 24HR 20 MG (BASE EQUIVALENT)	58180050107020	Brand
FETZIMA	LEVOMILNACIPRAN HCL CAP SR 24HR 40 MG (BASE EQUIVALENT)	58180050107040	Brand
FETZIMA	LEVOMILNACIPRAN HCL CAP SR 24HR 80 MG (BASE EQUIVALENT)	58180050107060	Brand
FETZIMA	LEVOMILNACIPRAN HCL CAP SR 24HR 120 MG (BASE EQUIVALENT)	58180050107080	Brand
FETZIMA TITRATION PACK	LEVOMILNACIPRAN HCL CAP SR 24HR 20 & 40 MG THERAPY PACK	5818005010B620	Brand
FETZIMA TITRATION PACK	LEVOMILNACIPRAN HCL CAP ER 24HR 20 & 40 MG THERAPY PACK	5818005010B620	Brand

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to any two of the following generics:

desvenlafaxine succinate extended-release (ER)

duloxetine

venlafaxine

venlafaxine ER

OR

2 - For continuation of prior therapy

3 . Endnotes

Treatment resistant depression should be defined after a minimum of two failed treatments with adequate dosing and duration; the minimal effective dosage administered for at least four weeks. [14]

4 . References

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Soleimani L, Lapidus KA, Losifescu DV. Diagnosis and treatment of major depressive disorder. Neurol Clin. 2011;29(1):177-93.

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Forfivo XL Prescribing Information. Almatica Pharma, Inc. Morristown, NJ. December 2019.

Sertraline capsules Prescribing Information. Almatica Pharma LLC. Morristown, NJ. October 2021.

Citalopram capsules Prescribing Information. Almatica Pharma LLC. Morristown, NJ. August 2023.

Venlafaxine besylate Prescribing Information. Almatica Pharma LLC. Morristown, NJ. August 2023.

Auvelity Prescribing Information. Axsome Therapeutics, Inc. New York, NY. December 2022.

Desvenlafaxine ER Prescribing Information. Alembic Pharmaceuticals Limited. Gujarat, India. January 2023.

Sforzini L, Worrell C, Kose M, et al. A Delphi-method-based consensus guideline for definition of treatment-resistant depression for clinical trials. Molecular Psychiatry. 2021;27(3):1286-1299.

Drizalma Prescribing Information. Sun Pharmaceutical Industries Limited. Mohali, India. May 2024.

5 . Revision History

Date	Notes
11/8/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-229171
Guideline Name	Oral Brand Tetracyclines
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/16/2010
P&T Revision Date:	6/19/2024

1 . Criteria

Product Name:Acticlate*, Avidoxy, Doryx, Doryx MPC*, Doxycycline Hyclate DR, LymePak, Minolira, Mondoxyne NL, Oracea, brand Solodyn, brand Targadox, brand Vibramycin	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
DORYX MPC	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 60 MG	04000020100615	Brand
SOLODYN	MINOCYCLINE HCL TAB ER 24HR 55 MG	04000040107522	Brand

SOLODYN	MINOCYCLINE HCL TAB ER 24HR 65 MG	04000040107525	Brand
SOLODYN	MINOCYCLINE HCL TAB ER 24HR 80 MG	04000040107528	Brand
SOLODYN	MINOCYCLINE HCL TAB ER 24HR 105 MG	04000040107533	Brand
SOLODYN	MINOCYCLINE HCL TAB ER 24HR 115 MG	04000040107535	Brand
ORACEA	DOXYCYCLINE (ROSACEA) CAP DELAYED RELEASE 40 MG	90060025006520	Brand
VIBRAMYCIN	DOXYCYCLINE MONOHYDRATE FOR SUSP 25 MG/5ML	04000020001905	Brand
VIBRAMYCIN	DOXYCYCLINE HYCLATE CAP 100 MG	04000020100110	Brand
MINOLIRA	MINOCYCLINE HCL TAB ER 24HR BIPHASIC RELEASE 105 MG	04000040107560	Brand
MINOLIRA	MINOCYCLINE HCL TAB ER 24HR BIPHASIC RELEASE 135 MG	04000040107570	Brand
DOXYCYCLINE HYCLATE DR	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 80 MG	04000020100624	Brand
TARGADOX	DOXYCYCLINE HYCLATE TAB 50 MG	04000020100305	Brand
DORYX	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 50 MG	04000020100610	Brand
DORYX MPC	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 120 MG	04000020100635	Brand
ACTICLATE	DOXYCYCLINE HYCLATE TAB 75 MG	04000020100307	Brand
ACTICLATE	DOXYCYCLINE HYCLATE TAB 150 MG	04000020100315	Brand
LYMEPAK	DOXYCYCLINE HYCLATE TAB 100 MG	04000020100310	Brand
DORYX	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 200 MG	04000020100650	Brand
TARGADOX	DOXYCYCLINE HYCLATE TAB 50 MG	04000020100305	Generic
AVIDOXY	DOXYCYCLINE MONOHYDRATE TAB 100 MG	04000020000310	Generic
MONDOXYNE NL	DOXYCYCLINE MONOHYDRATE CAP 100 MG	04000020000110	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) within the past 180 days or intolerance to one of the following generics:

doxycycline

minocycline

Notes	*Product may be excluded depending on the plan.

Product Name:Seysara	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
SEYSARA	SARECYCLINE HCL TAB 60 MG (BASE EQUIVALENT)	04000057100320	Brand
SEYSARA	SARECYCLINE HCL TAB 100 MG (BASE EQUIVALENT)	04000057100330	Brand
SEYSARA	SARECYCLINE HCL TAB 150 MG (BASE EQUIVALENT)	04000057100340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) within the past 180 days or intolerance to BOTH of the following generics:

doxycycline

minocycline

2 . Background

Benefit/Coverage/Program Information

Indications

Drug Name:Acticlate (doxycycline hyclate) tablets

Infections Indicated in the following conditions or diseases: 1. Rickettsial Infections: - Rocky Mountain spotted fever - typhus fever and the typhus group - Q fever - rickettsial pox - tick fevers caused by Rickettsiae 2. Sexually Transmitted Infections: - Uncomplicated urethral, endocervical or rectal infections caused by Chlamydia trachomatis. - Nongonococcal urethritis caused by Ureaplasma urealyticum. - Lymphogranuloma venereum caused by Chlamydia trachomatis. - Granuloma inguinale caused by Klebsiella granulomatis. - Uncomplicated gonorrhea caused by Neisseria gonorrhoeae. - Chancroid caused by Haemophilus ducreyi. 3. Respiratory Tract Infections: - Respiratory tract infections caused by Mycoplasma pneumoniae. - Psittacosis (ornithosis) caused by Chlamydophila psittaci. Because many strains of the following groups of microorganisms have been shown to be resistant to doxycycline, culture and susceptibility testing are recommended. Doxycycline is indicated for treatment of infections caused by the following microorganisms, when bacteriological testing indicates appropriate susceptibility to the drug: - Respiratory tract infections caused by Haemophilus influenzae. - Respiratory tract infections caused by Klebsiella species. - Upper respiratory infections caused by Streptococcus pneumoniae. 4. Specific Bacterial Infections: - Relapsing fever due to Borrelia recurrentis. - Plague due to Yersinia pestis. - Tularemia due to Francisella tularensis. - Cholera caused by Vibrio cholerae. - Campylobacter fetus infections caused by Campylobacter fetus. - Brucellosis due to Brucella species (in conjunction with streptomycin). - Bartonellosis due to Bartonella bacilliformis. Because many strains of the following groups of microorganisms have been shown to be resistant to doxycycline, culture and susceptibility testing are recommended. Doxycycline is indicated for treatment of infections caused by the following gram-negative microorganisms, when bacteriological testing indicates appropriate susceptibility to the drug: - Escherichia coli - Enterobacter aerogenes - Shigella species - Acinetobacter species - Urinary tract infections caused by Klebsiella species. 5. Ophthalmic Infections: - Trachoma caused by Chlamydia trachomatis, although the infectious agent is not always eliminated as judged by immunofluorescence. - Inclusion conjunctivitis caused by Chlamydia trachomatis. 6. Anthrax Including Inhalational Anthrax (Post-Exposure): Anthrax due to Bacillus anthracis, including inhalational anthrax (post-exposure): to reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis. 7. Alternative Treatment for Selected Infections when Penicillin is Contraindicated When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of the following infections: - Syphilis caused by Treponema pallidum. - Yaws caused by Treponema pallidum subspecies pertenue. - Listeriosis due to Listeria monocytogenes. - Vincent's infection caused by Fusobacterium fusiforme. - Actinomycosis caused by Actinomyces israelii. - Infections caused by Clostridium species. 8. Adjunctive Therapy for Acute Intestinal Amebiasis and Severe Acne: In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides. In severe acne, doxycycline may be useful adjunctive therapy. 9. Prophylaxis of

Malaria: Doxycycline is indicated for the prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (less than 4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Acticlate and other antibacterial drugs, Acticlate should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Drug Name: Doryx (doxycycline hyclate) delayed release tablets/Doryx MPC (doxycycline hyclate tablets, modified polymer coat), Doxycycline Delayed-Release (DR), Oracea (doxycycline delayed release)

Infections Indicated in the following conditions or diseases: 1. Rickettsial infections: - Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox, and tick fevers caused by Rickettsiae. 2. Sexually transmitted infections: - Uncomplicated urethral, endocervical or rectal infections in adults caused by Chlamydia trachomatis. - Nongonococcal urethritis caused by Ureaplasma urealyticum. - Lymphogranuloma venereum caused by Chlamydia trachomatis. - Granuloma inguinale caused by Calymmatobacterium granulomatis. 3. Respiratory tract infections - Respiratory tract infections caused by Mycoplasma pneumoniae. - Psittacosis (ornithosis) caused by Chlamydia psittaci. Because many strains of the following groups of microorganisms have been shown to be resistant to doxycycline, culture and susceptibility testing are recommended. Doxycycline is indicated for treatment of infections caused by the following microorganisms, when bacteriological testing indicates appropriate susceptibility to the drug: - Respiratory tract infections caused by Haemophilus influenzae. - Respiratory tract infections caused by Klebsiella species. - Upper respiratory infections caused by Streptococcus pneumoniae. 4. Specific bacterial infections: - Relapsing fever due to Borrelia recurrentis. - Plague due to Yersinia pestis. - Tularemia due to Francisella tularensis. - Cholera caused by Vibrio cholerae. - Campylobacter fetus infections caused by Campylobacter fetus. - Brucellosis due to Brucella species (in conjunction with streptomycin). - Bartonellosis due to Bartonella bacilliformis. Because many strains of the following groups of microorganisms have been shown to be resistant to doxycycline, culture and susceptibility testing are recommended. Doxycycline is indicated for treatment of infections caused by the following gram-negative microorganisms, when bacteriological testing indicates appropriate susceptibility to the drug: - Escherichia coli - Enterobacter aerogenes - Shigella species - Acinetobacter species - Urinary tract infections caused by Klebsiella species. 5. Ophthalmic infections - Trachoma caused by Chlamydia trachomatis, although the infectious agent is not always eliminated as judged by immunofluorescence. - Inclusion conjunctivitis caused by Chlamydia trachomatis. 6. Anthrax including inhalational anthrax (post-exposure): - Anthrax due to Bacillus anthracis, including inhalational anthrax (post-exposure): to reduce the incidence or progression of disease following exposure to

aerosolized Bacillus anthracis. 7. Alternative treatment for selected infections when penicillin is contraindicated: - When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of the following infections: - Syphilis caused by Treponema pallidum. - Yaws caused by Treponema pertenue. - Vincent's infection caused by Fusobacterium fusiforme. - Actinomycosis caused by Actinomyces israelii. - Infections caused by Clostridium species. 8. Adjunctive therapy for acute intestinal amebiasis and severe acne: - In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides. - In severe acne, doxycycline may be useful adjunctive therapy. 9. Prophylaxis of malaria - Doxycycline is indicated for the prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (<4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Doryx and other antibacterial drugs, Doryx should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Drug Name: Targadox (doxycycline hyclate) tablets

Infections Indicated in the following conditions or diseases: 1. Rickettsial infections: - Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox, and tick fevers caused by Rickettsiae. 2. Sexually transmitted infections: - Uncomplicated urethral, endocervical or rectal infections in adults caused by Chlamydia trachomatis. - Nongonococcal urethritis caused by Ureaplasma urealyticum. - Lymphogranuloma venereum caused by Chlamydia trachomatis. - Granuloma inguinale caused by Calymmatobacterium granulomatis. 3. Respiratory tract infections: - Respiratory tract infections caused by Mycoplasma pneumoniae. - Psittacosis (ornithosis) caused by Chlamydia psittaci. Because many strains of the following groups of microorganisms have been shown to be resistant to doxycycline, culture and susceptibility testing are recommended. Doxycycline is indicated for treatment of infections caused by the following microorganisms, when bacteriological testing indicates appropriate susceptibility to the drug: - Respiratory tract infections caused by Haemophilus influenzae. - Respiratory tract infections caused by Klebsiella species. - Upper respiratory infections caused by Streptococcus pneumoniae. 4. Specific bacterial infections: - Relapsing fever due to Borrelia recurrentis. - Plague due to Yersinia pestis. - Tularemia due to Francisella tularensis. - Cholera caused by Vibrio cholerae. - Campylobacter fetus infections caused by Campylobacter fetus. - Brucellosis due to Brucella species (in conjunction with streptomycin). - Bartonellosis due to Bartonella bacilliformis. Because many strains of the following groups of microorganisms have been shown to be resistant to doxycycline, culture and susceptibility testing are recommended. Doxycycline is indicated for treatment of infections caused by the following gram-negative microorganisms, when bacteriological testing indicates appropriate susceptibility to the drug: - Escherichia coli - Enterobacter aerogenes - Shigella species - Acinetobacter species - Urinary tract infections caused by

Klebsiella species. 5. Ophthalmic infections - Trachoma caused by Chlamydia trachomatis, although the infectious agent is not always eliminated as judged by immunofluorescence. - Inclusion conjunctivitis caused by Chlamydia trachomatis. 6. Anthrax including inhalational anthrax (post-exposure): - Anthrax due to Bacillus anthracis, including inhalational anthrax (post-exposure): to reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis. 7. Alternative treatment for selected infections when penicillin is contraindicated: - When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of the following infections: - Syphilis caused by Treponema pallidum. - Yaws caused by Treponema pertenue. - Vincent's infection caused by Fusobacterium fusiforme. - Actinomycosis caused by Actinomyces israelii. - Infections caused by Clostridium species. 8. Adjunctive therapy for acute intestinal amebiasis and severe acne: - In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides. - In severe acne, doxycycline may be useful adjunctive therapy. 9. Prophylaxis of malaria - Doxycycline is indicated for the prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (<4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains

Drug Name: Seysara (sarecycline) tablets

Acne vulgaris Indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older. Limitations of use: Efficacy of Seysara beyond 12 weeks and safety beyond 12 months have not been established. Seysara has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Seysara should be used only as indicated.

Drug Name: Minolira (minocycline hydrochloride) extended-release tablets

Acne vulgaris Indicated to treat the inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. Limitations of use: This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Minolira should be used only as indicated.

Drug Name: Vibramycin (doxycycline hyclate) capsules, Vibramycin (doxycycline monohydrate) powder for oral suspension, Vibramycin (doxycycline calcium) oral syrup

Infections Indicated for the treatment of the following infections: 1. Rocky mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox, and tick fevers caused by Rickettsiae. 2. Respiratory tract infections caused by Mycoplasma pneumoniae. 3. Lymphogranuloma venereum caused by Chlamydia trachomatis. 4. Psittacosis (ornithosis) caused by Chlamydophila psittaci. 5. Trachoma caused by Chlamydia trachomatis, although

the infectious agent is not always eliminated as judged by immunofluorescence. 6. Inclusion conjunctivitis caused by Chlamydia trachomatis. 7. Uncomplicated urethral, endocervical or rectal infections in adults caused by Chlamydia trachomatis. 8. Nongonococcal urethritis caused by Ureaplasma urealyticum. 9. Relapsing fever due to Borrelia recurrentis. Doxycycline is also indicated for the treatment of infections caused by the following gram-negative microorganisms: - Chancroid caused by Haemophilus ducreyi. - Plague due to Yersinia pestis (formerly Pasteurella pestis). - Tularemia due to Francisella tularensis. - Cholera caused by Vibrio cholerae. - Campylobacter fetus infections caused by Campylobacter fetus. - Brucellosis due to Brucella species (in conjunction with streptomycin). - Bartonellosis due to Bartonella bacilliformis. - Granuloma inguinale caused by Klebsiella granulomatis. Because many strains of the following groups of microorganisms have been shown to be resistant to doxycycline, culture and susceptibility testing are recommended. Doxycycline is indicated for treatment of infections caused by the following gram-negative bacteria, when bacteriologic testing indicates appropriate susceptibility to the drug: 1. Escherichia coli. 2. Enterobacter aerogenes. 3. Shigella species. 4. Acinetobacter species. 5. Respiratory tract infections caused by Haemophilus influenza. 6. Respiratory tract and urinary tract infections caused by Klebsiella species. Doxycycline is indicated for treatment of infections caused by the following gram-positive microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug: 1. Upper respiratory infections caused by Streptococcus pneumonia. 2. Anthrax due to Bacillus anthracis, including inhalational anthrax (post-exposure): to reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis. When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of the following infections: 1. Uncomplicated gonorrhea caused by Neisseria gonorrhoeae. 2. Syphilis caused by Treponema pallidum. 3. Yaws caused by Treponema pertenue. 4. Listeriosis due to Listeria monocytogenes. 5. Vincent's infection caused by Fusobacterium fusiforme, 6. Actinomycosis caused by Actinomyces israelii. 7. Infections caused by Clostridium species. In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides. In severe acne, doxycycline may be useful adjunctive therapy. Doxycycline is indicated for the prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (< 4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains. To reduce the development of drug-resistant bacteria and maintain effectiveness of Vibramycin and other antibacterial drugs, Vibramycin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Drug Name: Solodyn

Acne vulgaris Indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. Limitations of Use: Solodyn did not demonstrate any effect on non-inflammatory acne lesions. Safety of Solodyn has not

been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Solodyn should be used only as indicated.
Drug Name: LymePak (doxycycline hyclate) tablets
Lyme disease Indicated for the treatment of early Lyme disease (as evidenced by erythema migrans) due to Borrelia burgdorferi in adults and pediatric patients 8 years of age and older weighing 45 kg and above. Limitations of use: To reduce the development of drug-resistant bacteria and maintain the effectiveness of LymePak and other antibacterial drugs, LymePak should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

3 . References

Acticlate Prescribing Information. Aqua Pharmaceuticals. Exton, PA. October 2017.

Doryx Prescribing Information. Mayne Pharma. Greenville, NC. July 2022

Doryx MPC Prescribing Information. Mayne Pharma. Greenville, NC. June 2023.

Seysara Prescribing Information. Almirall, LLC. Exton, PA. March 2023.

Vibramycin Prescribing Information. Pfizer Labs. New York, NY. April 2021.

Minolira Prescribing Information. EPI Health, Inc. Charleston, SC. June 2018.

Targadox Prescribing Information. Journey Medical Corporation. Scottsdale, AZ. July 2020.

Oracea Prescribing Information. Galderma Laboratories, L.P. Forth Worth TX. January 2023.

Solodyn Prescribing Information. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ. December 2022.

LymePak Prescribing Information. Chartwell Pharmaceuticals, LLC. Congers, NY. November 2021.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228918
Guideline Name	Oral Fentanyl Products
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Actiq (fentanyl citrate) oral transmucosal lozenge
Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Actiq. This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Actiq is contraindicated in the management of acute or postoperative pain. Actiq is intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Actiq Q may be dispensed only to outpatients enrolled in the program. For inpatient administration of Actiq (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required. Not for use in opioid non-

tolerant patients. Not for use in the management of acute or postoperative pain, including headache/migraine and dental pain.

Drug Name: Fentora (fentanyl buccal tablet)

Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg/hr of transdermal fentanyl, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids while taking Fentora. This product must not be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Fentora is contraindicated in the management of acute or postoperative pain. Fentora is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Fentora may be dispensed only to outpatients enrolled in the program. For inpatient administration of Fentora (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required. Not for use in opioid non-tolerant patients. Not for use in the management of acute or postoperative pain, including headache/migraine and dental pain.

Drug Name: Lazanda (fentanyl) nasal spray

Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least: 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, 60 mg of oral hydrocodone/day, or an equianalgesic dose of another opioid for a week or longer. Patients must remain on around-the-clock opioids when taking Lazanda. Lazanda is contraindicated for patients who are not already tolerant to opioids because life-threatening respiratory depression and death could occur in patients not taking chronic opioids. For this reason, Lazanda is contraindicated in the management of acute or postoperative pain, including headache/migraine, or dental pain. Lazanda is intended to be prescribed only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Lazanda may be dispensed only to outpatients enrolled in the program.For inpatient administration of Lazanda (e.g., hospitals, hospices, and long-term care facilities that prescribefor inpatient use), patient enrollment is not required. Not for use in opioid non-tolerant patients. Not for use in the management of acute or postoperative pain, including headache/migraine and dental pain.

Drug Name: Subsys (fentanyl sublingual spray)

Breakthrough pain Indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for

their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Subsys . This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Subsys is contraindicated in the management of acute or postoperative pain. Subsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use As part of the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS Program, Subsys may be dispensed only to outpatients enrolled in the program. For inpatient administration (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use) of Subsys, patient enrollment is not required. Not for use in opioid non-tolerant patients. Not for use in the management of acute or postoperative pain, including headache/migraine and dental pain.

2 . Criteria

Product Name:Brand Actiq, Fentora*, Generic fentanyl citrate*, Lazanda*, or Subsys	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 200 MCG	65100025108450	Brand
ACTIQ	FENTANYL CITRATE LOLLIPOP 400 MCG	65100025108455	Brand
ACTIQ	FENTANYL CITRATE LOLLIPOP 600 MCG	65100025108460	Brand
ACTIQ	FENTANYL CITRATE LOLLIPOP 800 MCG	65100025108465	Brand
ACTIQ	FENTANYL CITRATE LOLLIPOP 1200 MCG	65100025108475	Brand
ACTIQ	FENTANYL CITRATE LOLLIPOP 1600 MCG	65100025108485	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 100 MCG (BASE EQUIV)	65100025100310	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 200 MCG (BASE EQUIV)	65100025100320	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 400 MCG (BASE EQUIV)	65100025100330	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 600 MCG (BASE EQUIV)	65100025100340	Brand

FENTORA	FENTANYL CITRATE BUCCAL TAB 800 MCG (BASE EQUIV)	65100025100350	Brand
LAZANDA	FENTANYL CITRATE NASAL SPRAY 100 MCG/ACT (BASE EQUIV)	65100025102050	Brand
LAZANDA	FENTANYL CITRATE NASAL SPRAY 400 MCG/ACT (BASE EQUIV)	65100025102060	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 100 MCG	65100025000910	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 200 MCG	65100025000920	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 400 MCG	65100025000930	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 600 MCG	65100025000940	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 800 MCG	65100025000950	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 1200 MCG (600 MCG X 2)	65100025000960	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 1600 MCG (800 MCG X 2)	65100025000970	Brand
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 200 MCG (BASE EQUIV)	65100025100320	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 400 MCG (BASE EQUIV)	65100025100330	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 600 MCG (BASE EQUIV)	65100025100340	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 800 MCG (BASE EQUIV)	65100025100350	Generic

Approval Criteria

1 - For the management of breakthrough cancer pain [A]

AND

2 - Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: [3, B]

Morphine sulfate at doses of greater than or equal to 60 mg/day

Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr

Oxycodone at a dose of greater than or equal to 30 mg/day

Oral hydromorphone at a dose of greater than or equal to 8 mg/day

Oral oxymorphone at a dose of greater than or equal to 25 mg/day

Oral hydrocodone at a dose of greater than or equal to 60mg/day

An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

3 - Trial and failure or intolerance to generic fentanyl lozenge

AND

4 - The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

5 - Prescribed by or in consultation with one of the following:

Pain specialist

Oncologist

Hematologist

Hospice care specialist

Palliative care specialist

Notes	*Product may be excluded depending on the plan

Product Name:Generic fentanyl lozenge	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 200 MCG	65100025108450	Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 400 MCG	65100025108455	Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 600 MCG	65100025108460	Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 800 MCG	65100025108465	Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 1200 MCG	65100025108475	Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 1600 MCG	65100025108485	Generic

Approval Criteria

1 - For the management of breakthrough cancer pain [A]

AND

2 - Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: [3, B]

Morphine sulfate at doses of greater than or equal to 60 mg/day

Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr

Oxycodone at a dose of greater than or equal to 30 mg/day

Oral hydromorphone at a dose of greater than or equal to 8 mg/day

Oral oxymorphone at a dose of greater than or equal to 25 mg/day

Oral hydrocodone at a dose of greater than or equal to 60mg/day

An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

4 - Prescribed by or in consultation with one of the following:

Pain specialist

Oncologist

Hematologist

Hospice care specialist

Palliative care specialist

Product Name:Brand Actiq, Fentora*, Generic fentanyl citrate*, Generic fentanyl lozenge, Lazanda*, or Subsys	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 200 MCG	65100025108450	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 200 MCG	65100025108450	Brand
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 400 MCG	65100025108455	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 400 MCG	65100025108455	Brand
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 600 MCG	65100025108460	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 600 MCG	65100025108460	Brand
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 800 MCG	65100025108465	Generic

ACTIQ	FENTANYL CITRATE LOLLIPOP 800 MCG	65100025108465	Brand
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 1200 MCG	65100025108475	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 1200 MCG	65100025108475	Brand
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 1600 MCG	65100025108485	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 1600 MCG	65100025108485	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 100 MCG (BASE EQUIV)	65100025100310	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 200 MCG (BASE EQUIV)	65100025100320	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 400 MCG (BASE EQUIV)	65100025100330	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 600 MCG (BASE EQUIV)	65100025100340	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 800 MCG (BASE EQUIV)	65100025100350	Brand
LAZANDA	FENTANYL CITRATE NASAL SPRAY 100 MCG/ACT (BASE EQUIV)	65100025102050	Brand
LAZANDA	FENTANYL CITRATE NASAL SPRAY 400 MCG/ACT (BASE EQUIV)	65100025102060	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 100 MCG	65100025000910	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 200 MCG	65100025000920	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 400 MCG	65100025000930	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 600 MCG	65100025000940	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 800 MCG	65100025000950	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 1200 MCG (600 MCG X 2)	65100025000960	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 1600 MCG (800 MCG X 2)	65100025000970	Brand
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 200 MCG (BASE EQUIV)	65100025100320	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 400 MCG (BASE EQUIV)	65100025100330	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 600 MCG (BASE EQUIV)	65100025100340	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 800 MCG (BASE EQUIV)	65100025100350	Generic

Approval Criteria

1 - For the management of breakthrough cancer pain

AND

2 - Prescribed by or in consultation with one of the following:

Pain specialist

Oncologist

Hematologist

Hospice care specialist

Palliative care specialist

AND

3 - The prescriber maintains and provides chart documentation of the patient's evaluation, including all of the following: [3]

An appropriate patient medical history and physical examination

A description of the nature and intensity of the pain

Documentation of appropriate dose escalation

Documentation of ongoing, periodic review of the course of opioid therapy

An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function)

Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian

Notes	*Product may be excluded depending on the plan.

3 . Endnotes

Actiq, Fentora, Lazanda, and Subsys are intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain [1, 2, 4, 5]

Actiq, Fentora, Lazanda, and Subsys are only intended for patients who are opioid tolerant. Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily, at least 60 mg of oral hydrocodone daily, or an equianalgesic dose of another opioid for a week or longer. [1, 2, 4, 5]

4 . References

Actiq Prescribing Information. Cephalon. North Wales, PA. March 2021.

Fentora Prescribing Information. Cephalon. North Wales, PA. December 2023.

American Academy of Pain Medicine. The use of opioids for the treatment of chronic pain (2013). Available at: http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf. Accessed August 12, 2020.

Lazanda Prescribing Information. West Therapeutic Development, LLC. March 2021.

Subsys Prescribing Information. INSYS Therapeutics, Inc. Chandler, AZ. April 2021.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229078
Guideline Name	Orencia (abatacept)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Orencia (abatacept) SC
Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis. Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic disease-modifying antirheumatic drugs [DMARDs], Janus kinase [JAK] inhibitors) is not recommended. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended. **Psoriatic Arthritis (PsA)** Indicated for the treatment of patients 2 years of age and older with active psoriatic arthritis (PsA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.
Drug Name: Orencia (abatacept) IV
Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis. Limitations of Use: The concomitant use of Orencia with

other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.

Polyarticular Juvenile Idiopathic Arthritis (PJIA) Indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.

Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis (PsA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.

Prophylaxis for Acute Graft versus Host Disease (aGVHD) Indicated for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor. Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.

2 . Criteria

Product Name:Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORENCIA CLICKJECT	ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML	6640001000D520	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML	6640001000E510	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML	6640001000E515	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML	6640001000E520	Brand
ORENCIA	ABATACEPT FOR IV SOLN 250 MG	66400010002120	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

methotrexate

leflunomide

sulfasalazine

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product**

Simponi (golimumab)

Rinvoq (upadacitinib)

Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy	
Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor. ** For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name:Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORENCIA CLICKJECT	ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML	6640001000D520	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML	6640001000E510	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML	6640001000E515	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML	6640001000E520	Brand
ORENCIA	ABATACEPT FOR IV SOLN 250 MG	66400010002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Orencia IV or Orencia SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORENCIA CLICKJECT	ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML	6640001000D520	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML	6640001000E510	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML	6640001000E515	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML	6640001000E520	Brand
ORENCIA	ABATACEPT FOR IV SOLN 250 MG	66400010002120	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

leflunomide

methotrexate

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

Enbrel (etanercept)

One formulary adalimumab product**

Rinvoq/LQ (upadacitinib)

Xeljanz (tofacitinib)

OR

4.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

Notes	* Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor. ** For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name:Orencia IV or Orencia SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORENCIA CLICKJECT	ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML	6640001000D520	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML	6640001000E510	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML	6640001000E515	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML	6640001000E520	Brand
ORENCIA	ABATACEPT FOR IV SOLN 250 MG	66400010002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Orencia IV or Orencia SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORENCIA CLICKJECT	ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML	6640001000D520	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML	6640001000E510	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML	6640001000E515	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML	6640001000E520	Brand
ORENCIA	ABATACEPT FOR IV SOLN 250 MG	66400010002120	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [5]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following:

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product**

Simponi (golimumab)

One formulary ustekinumab product**

Cosentyx (secukinumab)

Skyrizi (risankizumab-rzaa)

Tremfya (guselkumab)

Rinvoq/LQ (upadacitinib)

Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

Notes	** For review process only: Refer to the table in the Background section for carrier-specific formulary products

Product Name:Orencia IV or Orencia SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORENCIA CLICKJECT	ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML	6640001000D520	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML	6640001000E510	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML	6640001000E515	Brand
ORENCIA	ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML	6640001000E520	Brand
ORENCIA	ABATACEPT FOR IV SOLN 250 MG	66400010002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

Product Name:Orencia IV	
Diagnosis	Prophylaxis for Acute Graft versus Host Disease (aGVHD)
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORENCIA	ABATACEPT FOR IV SOLN 250 MG	66400010002120	Brand

Approval Criteria

1 - Used for prophylaxis of acute graft versus host disease (aGVHD)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

AND

4 - Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT

AND

5 - Used in combination with both of the following:

calcineurin inhibitor (e.g., cyclosporine, tacrolimus)

methotrexate

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products **Adalimumab-adaz** **Hyrimoz** **Hadlima** **Adalimumab-fkjp** **Formulary Ustekinumab Products** **Stelara**

4 . References

Orencia prescribing information. Bristol-Myers Squibb Company. Princeton, NJ. October 2023.

Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.

Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.

Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.

Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

5 . Revision History

Date	Notes
12/20/2024	New program

Prior Authorization Guideline

Guideline ID	GL-228920
Guideline Name	Orgovyx (relugolix)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Orgovyx (relugolix)
Prostate Cancer Indicated for the treatment of adult patients with advanced prostate cancer.

2 . Criteria

Product Name:Orgovyx	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

ORGOVYX	RELUGOLIX TAB 120 MG	21405570000320	Brand

Approval Criteria

1 - Diagnosis of advanced prostate cancer

AND

2 - Disease is one of the following:

Evidence of biochemical or clinical relapse following local primary intervention with curative intent

Newly diagnosed androgen-sensitive metastatic disease

Advanced localized disease unlikely to be cured by local primary intervention with curative intent

Product Name:Orgovyx	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORGOVYX	RELUGOLIX TAB 120 MG	21405570000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Documentation of serum testosterone level less than 50 ng/dL

3 . References

Orgovyx Prescribing Information. Myovant Sciences, Inc. Brisbane, CA. August 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules), Myfembree (relugolix, estradiol, and norethindrone acetate)

Prior Authorization Guideline

Guideline ID	GL-228502
Guideline Name	Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules), Myfembree (relugolix, estradiol, and norethindrone acetate)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules)
Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids) Indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Limitations of Use: Use should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.
Drug Name: Myfembree (relugolix, estradiol, and norethindrone acetate)
Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids) Indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Limitations of Use: Use should be limited to 24 months due to the risk of continued bone loss, which may not be reversible. **Pain Associated With Endometriosis** Indicated for the management of moderate to severe

pain associated with endometriosis in premenopausal women. Limitations of Use: Use should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

2 . Criteria

Product Name:Oriahnn, Myfembree	
Diagnosis	Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids)
Approval Length	12 month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORIAHNN	ELAGOLIX-ESTRAD-NORETH 300-1-0.5MG & ELAGOLIX 300MG CAP PACK	2499350340B220	Brand
MYFEMBREE	RELUGOLIX-ESTRADIOL-NORETHINDRONE ACETATE TAB 40-1-0.5 MG	24993503800320	Brand

Approval Criteria

1 - Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)

AND

2 - Patient is premenopausal

AND

3 - One of the following: [3, 5-6]

3.1 History of inadequate control of bleeding following a trial of at least 3 months, or history of intolerance or contraindication to one of the following:

Combination (estrogen/progestin) contraceptive

Progestins

Tranexamic acid

OR

3.2 Patient has had a previous interventional therapy to reduce bleeding [B]

AND

4 - Treatment duration of therapy has not exceeded a total of 24 months [C]

Product Name:Oriahnn, Myfembree	
Diagnosis	Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids)
Approval Length	12 months(s) [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORIAHNN	ELAGOLIX-ESTRAD-NORETH 300-1-0.5MG & ELAGOLIX 300MG CAP PACK	2499350340B220	Brand
MYFEMBREE	RELUGOLIX-ESTRADIOL-NORETHINDRONE ACETATE TAB 40-1-0.5 MG	24993503800320	Brand

Approval Criteria

1 - Patient has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.)

AND

2 - Treatment duration of therapy has not exceeded a total of 24 months [C]

Product Name:Myfembree	
Diagnosis	Pain Associated With Endometriosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MYFEMBREE	RELUGOLIX-ESTRADIOL-NORETHINDRONE ACETATE TAB 40-1-0.5 MG	24993503800320	Brand

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Patient is premenopausal

AND

3 - ONE of the following:

3.1 History of inadequate pain control response following a trial of 30 days, or history of intolerance or contraindication to one of the following:

Danazol

Combination (estrogen/progestin) contraceptive

Progestins

OR

3.2 Patient has had surgical ablation to prevent recurrence

AND

4 - Treatment duration of Myfembree has not exceeded a total of 24 months [C, 2]

Product Name:Myfembree	
Diagnosis	Pain Associated With Endometriosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MYFEMBREE	RELUGOLIX-ESTRADIOL-NORETHINDRONE ACETATE TAB 40-1-0.5 MG	24993503800320	Brand

Approval Criteria

1 - Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain)

AND

2 - Treatment duration of Myfembree has not exceeded a total of 24 months [C, 2]

3 . Endnotes

Results of UF-EXTEND and LIBERTY Extension demonstrated that up to 12 months of elagolix or relugolix with addback therapy provided sustained efficacy in reducing menstrual blood loss with no new or unexpected adverse effects compared with results of the preceding 6-month UF-1, UF-2, LIBERTY 1, and LIBERTY 2 studies. [4, 7]

Alternatives to surgery include oral contraceptives, progestins, tranexamic acid, and a variety of interventional therapies (e.g., uterine-artery embolization and magnetic resonance–guided focused ultrasonography) [3, 5-6]

Use of Oriahnn and Myfembree should be limited to 24 months due to the risk of continued bone loss, which may not be reversible. [1, 2]

4 . References

Oriahnn Prescribing Information. AbbVie Inc. North Chicago, IL. June 2023.

Myfembree Prescribing Information. Myovant Sciences, Inc. Brisbane, CA. April 2024.

Schlaff WD, Ackerman RT, Al-Hendy A, et al. Elagolix for Heavy Menstrual Bleeding in Women with Uterine Fibroids. N Engl J Med. 2020;382(4): 328-340.

Simon JA, Al-Hendy A, Archer DF, et al. Elagolix Treatment for Up to 12 Months in Women With Heavy Menstrual Bleeding and Uterine Leiomyomas. Obstet Gynecol. 2020;135(6):1313-1326.

De La Cruz MS, Buchanan EM. Uterine Fibroids: Diagnosis and Treatment. Am Fam Physician. 2017 Jan 15;95 (2): 100-107. Available by subscription at: https://www.aafp.org/afp/2017/0115/p100.html. Accessed June 8, 2021.

Stewart EA. Uterine Fibroids (Leiomyomas): Treatment Overview. UpToDate. Available by subscription at: https://www.uptodate.com. Accessed July 14, 2022.

Al-Hendy A, Lukes AS, Poindexter A, et al. LIBERTY: Long-term Extension Study Demonstrating One-year Efficacy and Safety of Relugolix Combination Therapy in Women with Symptomatic Uterine Fibroids. ASRM Scientific Congress & Expo. October 2020. Available at: https://asrm.confex.com/asrm/2020/meetingapp.cgi/Paper/7846. Accessed July 27, 2021.

Nezhat, C., Vang, N. et al. Optimal Management of Endometriosis and Pain. Obstetrics & Gynecology: October 2019 - Vol. 134, Issue 4, p 834-839. Available at https://journals.lww.com/greenjournal/pages/articleviewer.aspx?year=2019&issue=10000&article=00025&type=Fulltext. Accessed September 10, 2022.

Prior Authorization Guideline

Guideline ID	GL-228705
Guideline Name	Orilissa (elagolix)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Orilissa (elagolix)
Endometriosis Indicated for the management of moderate to severe pain associated with endometriosis. Limitations of Use: Limit the duration of use based on the dose and coexisting condition.

2 . Criteria

Product Name:Orilissa 150 mg	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORILISSA	ELAGOLIX SODIUM TAB 150 MG (BASE EQUIV)	30090030100320	Brand

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - One of the following: [2, 3]

2.1 History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following:

Danazol

Combination (estrogen/progesterone) oral contraceptive

Progestins

OR

2.2 Patient has had surgical ablation to prevent recurrence

Product Name:Orilissa 150 mg	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORILISSA	ELAGOLIX SODIUM TAB 150 MG (BASE EQUIV)	30090030100320	Brand

Approval Criteria

1 - Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain)

AND

2 - Treatment duration of Orilissa has not exceeded a total of 24 months [1]

Product Name:Orilissa 200 mg*	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORILISSA	ELAGOLIX SODIUM TAB 200 MG (BASE EQUIV)	30090030100330	Brand

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - One of the following: [2, 3]

2.1 History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following:

Danazol

Combination (estrogen/progesterone) oral contraceptive

Progestins

OR

2.2 Patient has had surgical ablation to prevent recurrence

Notes	*NOTE: Orilissa 200 mg is used for a maximum of 6 months.

3 . References

Orilissa prescribing information. AbbVie Inc. North Chicago, IL. June 2023.

Taylor H, Giudice L, Lessey B, et al. Treatment of endometriosis-associated pain with Elagolix, an oral GnRH Antagonist. N Engl J Med 2017; 377:28-40.

Armstrong C. ACOG Updates Guideline on Diagnosis and Treatment of Endometriosis. Am Fam Physician. 2011 Jan 1;83 (1): 84-85. Available by subscription at: https://www.aafp.org/afp/2011/0101/p84.html. Accessed July 30, 2024.

Prior Authorization Guideline

Guideline ID	GL-228925
Guideline Name	Orkambi (lumacaftor/ivacaftor)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Orkambi (lumacaftor/ivacaftor)
Cystic fibrosis (CF) Indicated for the treatment of cystic fibrosis (CF) in patients age 1 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. Limitations of Use: The efficacy and safety of Orkambi have not been established in patients with CF other than those homozygous for the F508del mutation.

2 . Criteria

Product Name:Orkambi (100 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORKAMBI	LUMACAFTOR-IVACAFTOR TAB 100-125 MG	45309902300310	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

Specialist affiliated with a cystic fibrosis care center

Pulmonologist

Product Name:Orkambi (200 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

ORKAMBI	LUMACAFTOR-IVACAFTOR TAB 200-125 MG	45309902300320	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

Specialist affiliated with a cystic fibrosis care center

Pulmonologist

Product Name:Orkambi (100 mg - 125 mg) tablet, Orkambi (200 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORKAMBI	LUMACAFTOR-IVACAFTOR TAB 200-125 MG	45309902300320	Brand
ORKAMBI	LUMACAFTOR-IVACAFTOR TAB 100-125 MG	45309902300310	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

Product Name:Orkambi (100 mg - 125 mg) granules packet, Orkambi (150 mg - 188 mg) granules packet, Orkambi (75 mg - 94 mg) granules packet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 100-125 MG	45309902303010	Brand
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 150-188 MG	45309902303020	Brand
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 75-94 MG	45309902303005	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - One of the following:

3.1 Patient is 1 through 5 years of age

OR

3.2 Both of the following:

Patient is 6 years of age or greater

Patient is unable to swallow oral tablets

AND

4 - Prescribed by or in consultation with one of the following:

Specialist affiliated with a cystic fibrosis care center

Pulmonologist

Product Name:Orkambi (100 mg - 125 mg) granules packet, Orkambi (150 mg - 188 mg) granules packet, Orkambi (75 mg - 94 mg) granules packet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 100-125 MG	45309902303010	Brand
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 150-188 MG	45309902303020	Brand
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 75-94 MG	45309902303005	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

AND

2 - One of the following:

2.1 Patient is 1 through 5 years of age

OR

2.2 Both of the following:

Patient is 6 years of age or greater

Patient is unable to swallow oral tablets

3 . References

Orkambi Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. August 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Orserdu (elacestrant)

Prior Authorization Guideline

Guideline ID	GL-228924
Guideline Name	Orserdu (elacestrant)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Orserdu (elacestrant)
Breast Cancer Indicated for the treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

2 . Criteria

Product Name:Orserdu	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORSERDU	ELACESTRANT HYDROCHLORIDE TAB 86 MG	21403720100320	Brand
ORSERDU	ELACESTRANT HYDROCHLORIDE TAB 345 MG	21403720100340	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

Advanced

Metastatic

AND

3 - Disease is estrogen receptor (ER)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of estrogen receptor (ESR1) mutation(s) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)] [A, 1, 3]

Product Name:Orserdu	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORSERDU	ELACESTRANT HYDROCHLORIDE TAB 86 MG	21403720100320	Brand
ORSERDU	ELACESTRANT HYDROCHLORIDE TAB 345 MG	21403720100340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

Per clinical consult, treatment can be with an aromatase inhibitor, with or without fulvestrant, with or without CD4/6 inhibitors, as not all patients are candidates for CD4/6 inhibitors [3]

4 . References

Orserdu Prescribing Information. Stemline Therapeutics, Inc., New York, NY. January 2023.

Clinicaltrials.gov. Phase 3 Trial of Elacestrant vs. Standard of Care for the Treatment of Patients With ER+/HER2- Advanced Breast Cancer (EMERALD). Available at https://www.clinicaltrials.gov/ct2/results?cond=&term=nct03778931&cntry=&state=&city=&dist=. Accessed March 7, 2023.

Clinical Consult with an oncologist. March 16, 2023.

National Comprehensive Cancer Network(NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. V3.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 16, 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228929
Guideline Name	Otezla (apremilast)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Otezla (apremilast)
Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis. **Plaque Psoriasis (PsO)** Indicated for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy. Indicated for pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. **Oral Ulcers Associated with Behçet's Disease** Indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

2 . Criteria

Product Name:Otezla	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [2]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

Product Name:Otezla	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 2]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

Product Name:Otezla	
Diagnosis	Plaque psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 4 X 10 MG & 51 X 20 MG	6670001500B710	Brand
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 20 MG	66700015000320	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Both of the following:

Patient is 6 years of age or older

Patient weighs at least 20 kg

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Otezla	
Diagnosis	Plaque psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 4 X 10 MG & 51 X 20 MG	6670001500B710	Brand
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 20 MG	66700015000320	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1, 4]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Otezla	
Diagnosis	Oral Ulcers Associated with Behçet's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Diagnosis of Behçet's Disease

AND

2 - Patient has active oral ulcers

Product Name:Otezla	
Diagnosis	Oral Ulcers Associated with Behçet's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy(e.g., reduction in pain from oral ulcers or reduction in number of oral ulcers)

3 . References

Otezla Prescribing Information. Amgen Inc. Thousand Oaks, CA. April 2024.

Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228503
Guideline Name	Overactive Bladder Agents - Step Therapy
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Gelnique (oxybutynin chloride)
Overactive Bladder Symptoms Indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.
Drug Name: Oxytrol (oxybutynin transdermal system)
Overactive Bladder Symptoms Indicated for the treatment of overactive bladder in men with symptoms of urge urinary incontinence, urgency, and frequency.
Drug Name: Oxytrol For Women (oxybutynin patch)
Overactive Bladder Symptoms Indicated for the treatment of overactive bladder in women with symptoms of urge urinary incontinence, urgency, and frequency.
Drug Name: Gemtesa (vibegron)
Overactive Bladder Symptoms Indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.

Drug Name: Vesicare LS (solifenacin) Oral Suspension
Neurogenic Detrusor Overactivity Indicated for the treatment of neurogenic detrusor overactivity in pediatric patients aged 2 years and older.

Drug Name: Toviaz (fesoterodine fumarate)
Overactive Bladder Indicated for the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency. **Neurogenic Detrusor Overactivity** Indicated for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 6 years of age and older with a body weight greater than 25 kg.

2 . Criteria

Product Name:Gelnique, Gemtesa, Oxytrol, Oxytrol For Women, Toviaz	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
GELNIQUE	OXYBUTYNIN CHLORIDE TD GEL 10%	54100045204030	Brand
OXYTROL	OXYBUTYNIN TD PATCH TWICE WEEKLY 3.9 MG/24HR	54100045008720	Brand
GEMTESA	VIBEGRON TAB 75 MG	54200080000320	Brand
TOVIAZ	FESOTERODINE FUMARATE TAB ER 24HR 4 MG	54100020207520	Brand
TOVIAZ	FESOTERODINE FUMARATE TAB ER 24HR 8 MG	54100020207530	Brand
OXYTROL FOR WOMEN	OXYBUTYNIN TD PATCH TWICE WEEKLY 3.9 MG/24HR	54100045008720	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to two of the following: [3]

Myrbetriq tablets

generic darifenacin ER

generic oxybutynin IR/ER

generic solifenacin

generic tolterodine IR/ER

generic trospium IR/ER

generic fesoterodine ER

Product Name:Vesicare LS	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
VESICARE LS	SOLIFENACIN SUCCINATE SUSP 5 MG/5ML (1 MG/ML)	54100055201820	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to one of the following:

generic oxybutynin IR/ER tablets

generic oxybutynin syrup

3 . References

Gelnique Prescribing Information. Allergan USA, Inc. Irvine, CA. March 2019.

Oxytrol Prescribing Information. Allergan USA, Inc. Irvine, CA. November 2023.

American Urological Association. Guideline on Diagnosis and Treatment of Non-Neurogenic Overactive Bladder (OAB) in Adults (2019). https://www.auanet.org/guidelines/overactive-bladder-(oab)-guideline. Accessed February 14, 2022.

Gemtesa Prescribing Information. Urovant Sciences, Inc. July 2023.

Vesicare LS Prescribing Information. Astellas Pharma US, Inc. Northbrook, IL. October 2022.

Toviaz Prescribing Information. Pfizer Inc. New York, NY. November 2021.

Oxytrol for Women. Allergan USA, Inc., Madison, NJ. August 2016.

Prior Authorization Guideline

Guideline ID	GL-228505
Guideline Name	Oxbryta (voxelotor) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Oxbryta (voxelotor)
Sickle Cell Disease Indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 4 years of age and older. This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name:Oxbryta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OXBRYTA	VOXELOTOR TAB 500 MG	82805080000320	Brand
OXBRYTA	VOXELOTOR TAB FOR ORAL SUSP 300 MG	82805080007320	Brand
OXBRYTA	VOXELOTOR TAB 300 MG	82805080000310	Brand

Approval Criteria

1 - Diagnosis of sickle cell disease

AND

2 - Patient is 4 years of age and older

AND

3 - Patient demonstrates hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation [2]

AND

4 - Trial and failure or inadequate response, contraindication, or intolerance to hydroxyurea [3, 4]

AND

5 - Prescribed by or in consultation with one of the following:

Hematologist/Oncologist

Specialist with expertise in the diagnosis and management of sickle cell disease

Product Name:Oxbryta

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OXBRYTA	VOXELOTOR TAB 500 MG	82805080000320	Brand
OXBRYTA	VOXELOTOR TAB FOR ORAL SUSP 300 MG	82805080007320	Brand
OXBRYTA	VOXELOTOR TAB 300 MG	82805080000310	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., an increase in hemoglobin level of greater than or equal to 1 g/dL from baseline, decreased annualized incidence rate of VOCs)

AND

2 - Patient demonstrates hemoglobin level that does not exceed 10.5 g/dL

Product Name:Oxbryta	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OXBRYTA	VOXELOTOR TAB 500 MG	82805080000320	Brand
OXBRYTA	VOXELOTOR TAB FOR ORAL SUSP 300 MG	82805080007320	Brand
OXBRYTA	VOXELOTOR TAB 300 MG	82805080000310	Brand

Approval Criteria

1 - Diagnosis of sickle cell disease

AND

2 - Patient is 4 years of age and older

AND

3 - Patient demonstrates hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation [2]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or inadequate response, contraindication, or intolerance to hydroxyurea [3, 4]

AND

5 - Prescribed by or in consultation with one of the following:

Hematologist/Oncologist

Specialist with expertise in the diagnosis and management of sickle cell disease

3 . References

Oxbryta (voxelotor) [Prescribing Information]. South San Francisco, CA. Global Blood Therapeutics, Inc; August 2023.

Vichinsky E, Hoppe C, Ataga K et al. A Phase 3 Randomized Trial of Voxelotor in Sickle Cell Disease. New England Journal of Medicine. 2019;381(6):509-519. doi:10.1056/nejmoa1903212.

Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. Nhlbi.nih.gov. https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Published 2014. Accessed December 1, 2021.

Brawley O, Cornelius L, Edwards L et al. National Institutes of Health Consensus Development Conference Statement: Hydroxyurea Treatment for Sickle Cell Disease. Ann Intern Med. 2008;148(12):932. doi:10.7326/0003-4819-148-12-200806170-00220.

Prior Authorization Guideline

Guideline ID	GL-228507
Guideline Name	Oxervate (cenegermin-bkbj) - PA, QL
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Oxervate (cenegermin-bkbj)
Neurotrophic Keratitis (NK) Indicated for the treatment of neurotrophic keratitis (NK).

2 . Criteria

Product Name:Oxervate	
Approval Length	8 weeks*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

OXERVATE	CENEGERMIN-BKBJ OPHTH SOLN 0.002% (20 MCG/ML)	86770020202020	Brand

Approval Criteria

1 - Diagnosis of neurotrophic keratitis

AND

2 - Trial and failure or intolerance to at least one over-the-counter ocular lubricant used at an optimal dose and frequency for at least two weeks (e.g., artificial tears, lubricating gels/ointments, etc.) [3]

AND

3 - Prescribed by or in consultation with an ophthalmologist

Notes	*Initial authorization maximum coverage is limited to one 8-week approval. Oxervate is hard-coded with a quantity limit of 112 mL per lifetime.

Product Name:Oxervate	
Approval Length	One 8-Week Approval*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OXERVATE	CENEGERMIN-BKBJ OPHTH SOLN 0.002% (20 MCG/ML)	86770020202020	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Provider attests patient is being treated for disease recurrence (e.g., new corneal damage following prior corneal healing)

AND

1.1.2 Provider attests patient has not experienced treatment failure (e.g., patient has not experienced corneal healing after a previous course of Oxervate)

OR

1.2 Provider attests treatment is for an eye that has not previously been treated with Oxervate

Notes	*Reauthorization maximum coverage is limited to one 8-week approval. Oxervate is hard-coded with a quantity limit of 112 mL per lifetime. Subsequent request will be denied for off-label

Product Name:Oxervate	
Guideline Type	Quantity Limit*

Product Name	Generic Name	GPI	Brand/Generic
OXERVATE	CENEGERMIN-BKBJ OPHTH SOLN 0.002% (20 MCG/ML)	86770020202020	Brand

Approval Criteria

1 - Requests for additional quantity will not be approved

Notes	*Requests will be denied off-label.

3 . References

Oxervate Prescribing Information. Dompe U.S. Inc. Boston, MA. October 2023.

FDA Medical Review: Oxervate. Drugs at FDA Web site. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761094Orig1s000MedR.pdf. Accessed April 1, 2021.

Per clinical consult with ophthalmologist, December 12, 2018.

Oxlumo (lumasiran)

Prior Authorization Guideline

Guideline ID	GL-228509
Guideline Name	Oxlumo (lumasiran)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Oxlumo (lumasiran) injection
Primary Hyperoxaluria Type 1 Indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.

2 . Criteria

Product Name:Oxlumo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OXLUMO	LUMASIRAN SODIUM SUBCUTANEOUS SOLN 94.5 MG/0.5ML	56626040202020	Brand

Approval Criteria

1 - Diagnosis of primary hyperoxaluria type 1 (PH1)

AND

2 - Diagnosis has been confirmed by both of the following:

2.1 One of the following:

Elevated urinary oxalate excretion

Elevated plasma oxalate concentration

Spot urinary oxalate to creatinine molar ratio greater than normal for age

AND

2.2 One of the following:

Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene

Liver biopsy demonstrating absence or reduced alanine:glyoxylate aminotransferase (AGT) activity

AND

3 - Patient has not received a liver transplant

AND

4 - Prescribed by or in consultation with one of the following:

Hepatologist

Nephrologist

Urologist

Geneticist

Specialist with expertise in the treatment of PH1

Product Name:Oxlumo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OXLUMO	LUMASIRAN SODIUM SUBCUTANEOUS SOLN 94.5 MG/0.5ML	56626040202020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration)

AND

2 - Patient has not received a liver transplant

AND

3 - Prescribed by or in consultation with one of the following:

Hepatologist

Nephrologist

Urologist

Geneticist

Specialist with expertise in the treatment of PH1

3 . References

Oxlumo prescribing information. Alnylam Pharmaceuticals, Inc. Cambridge, MA. September 2023.

UptoDate: Primary hyperoxaluria. Available at https://www.uptodate.com/contents/primary-hyperoxaluria?search=primary%20hyperoxaluria%20type%201&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#H2667808272. Accessed January 3, 2024.

Prior Authorization Guideline

Guideline ID	GL-233188
Guideline Name	Palynziq (pegvaliase-pqpz) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	8/16/2018
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Palynziq (pegvaliase-pqpz)
Phenylketonuria (PKU) Indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

2 . Criteria

Product Name:Palynziq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PALYNZIQ	PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF SYRINGE 2.5 MG/0.5ML	3090855040E510	Brand
PALYNZIQ	PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF SYRINGE 10 MG/0.5ML	3090855040E520	Brand
PALYNZIQ	PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF SYRINGE 20 MG/ML	3090855040E530	Brand

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management (e.g., phenylalanine restricted diet, Kuvan [sapropterin])

AND

3 - One of the following:

3.1 Patient has had a trial and failure or intolerance to generic sapropterin

OR

3.2 Patient is not a candidate for generic sapropterin therapy due to the presence of two null mutations in trans

AND

4 - Patient will have phenylalanine blood levels measured every 4 weeks until a maintenance dose is established and periodically thereafter [A]

Product Name:Palynziq

Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PALYNZIQ	PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF SYRINGE 2.5 MG/0.5ML	3090855040E510	Brand
PALYNZIQ	PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF SYRINGE 10 MG/0.5ML	3090855040E520	Brand
PALYNZIQ	PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF SYRINGE 20 MG/ML	3090855040E530	Brand

Approval Criteria

1 - Patient has experienced an objective response to therapy, defined by one of the following [B, C]:

1.1 At least a 20% reduction in blood phenylalanine concentrations from pre-treatment baseline

OR

1.2 Blood phenylalanine concentrations less than or equal to 600 micromol/L

AND

2 - Patient will continue to have phenylalanine blood levels measured periodically during therapy [A]

Product Name:Palynziq	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PALYNZIQ	PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF SYRINGE 2.5 MG/0.5ML	3090855040E510	Brand

PALYNZIQ	PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF SYRINGE 10 MG/0.5ML	3090855040E520	Brand
PALYNZIQ	PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF SYRINGE 20 MG/ML	3090855040E530	Brand

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management (e.g., phenylalanine restricted diet, Kuvan [sapropterin])

AND

3 - Submission of medical records (e.g., chart notes) or paid claims for one of the following:

3.1 Patient has had a trial and failure or intolerance to generic sapropterin

OR

3.2 Patient is not a candidate for generic sapropterin therapy due to the presence of two null mutations in trans

AND

4 - Patient will have phenylalanine blood levels measured every 4 weeks until a maintenance dose is established and periodically thereafter [A]

3 . Endnotes

Patients should have blood phenylalanine (Phe) concentrations measured every 4 weeks after initiation of Palynziq (pegvaliase-pqpz), until a maintenance dosage is established. Periodic monitoring should continue after a maintenance dose is established [1].

Therapy should be discontinued in patients who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily. Based on the recommended dosing regimen, patients could be evaluated for discontinuation after 49 weeks of therapy. This would allow for induction, titration, maintenance on 20 mg for 24 weeks, and maintenance on 40mg for 16 weeks.

The American College of Medical Genetics and Genomics guideline suggests blood Phe levels should be maintained in the range of 120–360 micromol/L for all patients [2].

4 . References

Palynziq prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. November 2020.

Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014 Feb;16(2):188-200.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-233211
Guideline Name	Pancreatic Enzyme Products
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	8/21/2012
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Pancreaze (pancrelipase), Pertzye (pancrelipase)
Exocrine Pancreatic Insufficiency Indicated for the treatment of exocrine pancreatic insufficiency in adult and pediatric patients.
Drug Name: Viokace (pancrelipase)
Exocrine Pancreatic Insufficiency In combination with a proton pump inhibitor, is indicated for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy in adults.

2 . Criteria

Product Name:Pancreaze, Pertzye, Viokace	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
PANCREAZE	PANCRELIPASE (LIP-PROT-AMYL) DR CAP 4200-10000-17500 UNIT	51200024006710	Brand
PANCREAZE	PANCRELIPASE (LIP-PROT-AMYL) DR CAP 10500-25000-43750 UNIT	51200024006734	Brand
PANCREAZE	PANCRELIPASE (LIP-PROT-AMYL) DR CAP 16800-40000-70000 UNIT	51200024006750	Brand
PANCREAZE	PANCRELIPASE (LIP-PROT-AMYL) DR CAP 21000-37000-61000 UNIT	51200024006754	Brand
PERTZYE	PANCRELIPASE (LIP-PROT-AMYL) DR CAP 8000-28750-30250 UNIT	51200024006725	Brand
PERTZYE	PANCRELIPASE (LIP-PROT-AMYL) DR CAP 16000-57500-60500 UNIT	51200024006749	Brand
VIOKACE	PANCRELIPASE (LIP-PROT-AMYL) TAB 10440-39150-39150 UNIT	51200024000330	Brand
VIOKACE	PANCRELIPASE (LIP-PROT-AMYL) TAB 20880-78300-78300 UNIT	51200024000360	Brand
PERTZYE	PANCRELIPASE (LIP-PROT-AMYL) DR CAP 4000-14375-15125 UNIT	51200024006709	Brand
PERTZYE	PANCRELIPASE (LIP-PROT-AMYL) DR CAP 24000-86250-90750 UNIT	51200024006762	Brand
PANCREAZE	PANCRELIPASE (LIP-PROT-AMYL) DR CAP 2600-8800-15200 UNIT	51200024006703	Brand
PANCREAZE	PANCRELIPASE (LIP-PROT-AMYL) DR CAP 37000-97300-149900 UNIT	51200024006781	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to BOTH of the following:

Creon (pancrelipase) delayed-release capsules

Zenpep (pancrelipase) delayed-release capsules

3 . References

Pancreaze Prescribing Information. Vivus, Inc. Campbell, CA. February 2024.

Pertzye Prescribing Information. Digestive Care, Inc.; Bethlehem, PA. February 2024.

Viokace Prescribing Information. Allergan USA, Inc.; Irvine, CA. February 2024.

Creon Prescribing Information. AbbVie Inc.; North Chicago, IL. February 2024

Zenpep Prescribing Information. Allergan USA, Inc.; Irvine, CA. February 2024.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-233347
Guideline Name	PCSK9 Inhibitors - PA, ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/27/2025
P&T Approval Date:	5/20/2015
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Repatha (evolocumab)
Prevention of Cardiovascular Events Indicated to reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults with established cardiovascular disease **Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia)** Indicated as an adjunct to diet, alone or in combination with other low density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C. **Heterozygous Familial Hypercholesterolemia (HeFH)** Indicated as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C **Homozygous Familial Hypercholesterolemia** Indicated as an adjunct to other LDL-C-

lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C
Drug Name: Praluent (alirocumab)
Prevention of Cardiovascular Events Indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease. **Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia)** Indicated as an adjunct to diet, alone or in combination with other low density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C. **Heterozygous Familial Hypercholesterolemia (HeFH)** Indicated as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 8 years and older with HeFH to reduce LDL-C. **Homozygous Familial Hypercholesterolemia** Indicated as an adjunct to other LDL-C lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

2 . Criteria

Product Name:Repatha	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
REPATHA SURECLICK	EVOLOCUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML	3935002000D520	Brand
REPATHA	EVOLOCUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 140 MG/ML	3935002000E520	Brand
REPATHA PUSHTRONEX SYSTEM	EVOLOCUMAB SUBCUTANEOUS SOLN CARTRIDGE/INFUSOR 420 MG/3.5ML	3935002000E230	Brand

Approval Criteria

1 - One of the following diagnoses:

1.1 Both of the following:

Heterozygous familial hypercholesterolemia (HeFH)

Patient is 10 years of age or older

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD)

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following:

Patient has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy

Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)

Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following:

3.1 One of the following while on maximally tolerated lipid-lowering therapy (e.g., statins) within the last 120 days [5]:

Patient requires greater than or equal to 25% LDL-C reduction to achieve goal

Patient has LDL-C greater than or equal to 70 mg/dL with ASCVD

Patient has LDL-C greater than or equal to 100 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.2.2 LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

Product Name:Praluent (F)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - One of the following diagnoses:

1.1 Both of the following:

Heterozygous familial hypercholesterolemia (HeFH)

Patient is 8 years of age or older

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD)

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following:

Patient has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy

Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)

Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following:

3.1 One of the following while on maximally tolerated lipid-lowering therapy (e.g., statins) within the last 120 days [5]:

Patient requires greater than or equal to 25% LDL-C reduction to achieve goal

Patient has LDL-C greater than or equal to 70 mg/dL with ASCVD

Patient has LDL-C greater than or equal to 100 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.2.2 LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

AND

4 - For patients 10 years of age or older: Trial and failure, contraindication, or intolerance to Repatha

Product Name:Repatha, Praluent (F)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
REPATHA SURECLICK	EVOLOCUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML	3935002000D520	Brand
REPATHA	EVOLOCUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 140 MG/ML	3935002000E520	Brand
REPATHA PUSHTRONEX SYSTEM	EVOLOCUMAB SUBCUTANEOUS SOLN CARTRIDGE/INFUSOR 420 MG/3.5ML	3935002000E230	Brand

PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline

AND

2 - One of the following:

Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose

Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

3 - Applies to Praluent only: For patients 10 years of age or older: Trial and failure, contraindication, or intolerance to Repatha

Product Name:Praluent (NF)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand

PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - One of the following diagnoses:

1.1 Both of the following:

Heterozygous familial hypercholesterolemia (HeFH)

Patient is 8 years of age or older

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD)

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following:

Patient has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy

Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)

Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following:

3.1 Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following while on maximally tolerated lipid-lowering therapy (e.g., statins) within the last 120 days [5]:

Patient requires greater than or equal to 25% LDL-C reduction to achieve goal

Patient has LDL-C greater than or equal to 70 mg/dL with ASCVD

Patient has LDL-C greater than or equal to 100 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.2.2 Submission of medical records (e.g., laboratory values) documenting LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

AND

4 - For patients 10 years of age or older: Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha

Product Name:Praluent (NF)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline

AND

2 - One of the following:

Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose

Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

3 - For patients 10 years of age or older: Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha

Product Name:Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
REPATHA SURECLICK	EVOLOCUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML	3935002000D520	Brand

REPATHA	EVOLOCUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 140 MG/ML	3935002000E520	Brand
REPATHA PUSHTRONEX SYSTEM	EVOLOCUMAB SUBCUTANEOUS SOLN CARTRIDGE/INFUSOR 420 MG/3.5ML	3935002000E230	Brand

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following:

1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

OR

1.2 Both of the following:

1.2.1 Untreated LDL-C greater than 400 mg/dL

AND

1.2.2 One of the following:

Xanthoma before 10 years of age

Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - One of the following:

Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)

Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Patient is 10 years of age or older

Product Name:Praluent (F)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following:

1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

OR

1.2 Both of the following:

1.2.1 Untreated LDL-C greater than 400 mg/dL

AND

1.2.2 One of the following:

Xanthoma before 10 years of age

Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - One of the following:

Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)

Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Trial and failure, contraindication, or intolerance to Repatha

Product Name:Repatha, Praluent (F)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
REPATHA SURECLICK	EVOLOCUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML	3935002000D520	Brand
REPATHA	EVOLOCUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 140 MG/ML	3935002000E520	Brand
REPATHA PUSHTRONEX SYSTEM	EVOLOCUMAB SUBCUTANEOUS SOLN CARTRIDGE/INFUSOR 420 MG/3.5ML	3935002000E230	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline

AND

2 - One of the following:

Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe)

Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Applies to Praluent only: Trial and failure, contraindication, or intolerance to Repatha

Product Name:Praluent (NF)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following:

1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

OR

1.2 Both of the following:

1.2.1 Untreated LDL-C greater than 400 mg/dL

AND

1.2.2 One of the following:

Xanthoma before 10 years of age

Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - One of the following:

Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)

Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha

Product Name:Praluent (NF)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline

AND

2 - One of the following:

Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe)

Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha

3 . Endnotes

Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. [3]

4 . References

Praluent Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. March 2024.

Repatha Prescribing Information. Amgen Inc. Thousand Oaks, CA. November 2024.

Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of

Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.

Alonso R, Cuevas A, Cafferata A. Diagnosis and Management of Statin Intolerance. J Atheroscler Thromb. 2019 Mar 1;26(3):207-215. doi: 10.5551/jat.RV17030. Epub 2019 Jan 19. PMID: 30662020; PMCID: PMC6402887.

Lloyd-Jones D, Morris P, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. J Am Coll Cardiol. 2022 Oct, 80 (14) 1366–1418. https://doi.org/10.1016/j.jacc.2022.07.006

Harada-Shiba M, Arai H, Ishigaki Y, Ishibashi S, Okamura T, Ogura M, Dobashi K, Nohara A, Bujo H, Miyauchi K, Yamashita S, Yokote K; Working Group by Japan Atherosclerosis Society for Making Guidance of Familial Hypercholesterolemia. Guidelines for Diagnosis and Treatment of Familial Hypercholesterolemia 2017. J Atheroscler Thromb. 2018 Aug 1;25(8):751-770. doi: 10.5551/jat.CR003. Epub 2018 Jun 7. PMID: 29877295; PMCID: PMC6099072.

Cuchel M, Raal FJ, Hegele RA, et al. 2023 Update on European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolaemia: new treatments and clinical guidance. Eur Heart J. 2023;44(25):2277-2291. doi:10.1093/eurheartj/ehad197

5 . Revision History

Date	Notes
2/27/2025	Quartz Comm and EHB copied to mirrow OptumRx and EHB

Prior Authorization Guideline

Guideline ID	GL-233191
Guideline Name	Pedmark (sodium thiosulfate injection, solution)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	12/14/2022
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Pedmark (sodium thiosulfate injection, solution)
Prophylaxis of Cisplatin-Induced Ototoxicity. Indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors. Limitations of Use: The safety and efficacy of Pedmark have not been established when administered following cisplatin infusions longer than 6 hours. Pedmark may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

2 . Criteria

Product Name:Pedmark

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PEDMARK	SODIUM THIOSULFATE IV SOLN 125 MG/ML (12.5%)	21757375602020	Brand

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Disease is BOTH of the following:

Localized

Non-Metastatic

AND

3 - Used for the prevention of ototoxicity due to cisplatin-based chemotherapy

AND

4 - Patient is 1 month of age or older

AND

5 - Prescribed by or in consultation with an oncologist

3 . References

Pedmark Prescribing Information. Fennec Pharmaceuticals, Inc. Hoboken, NJ. September 2022.

Clinical Consult - Pediatric Hematology/Oncology specialist. November 15, 2022.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228511
Guideline Name	Pemazyre (pemigatinib) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Pemazyre (pemigatinib)
Cholangiocarcinoma Indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). **Myeloid/Lymphoid Neoplasms** Indicated for the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth factor receptor 1 (FGFR1) rearrangement.

2 . Criteria

Product Name:Pemazyre	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PEMAZYRE	PEMIGATINIB TAB 4.5 MG	21532260000320	Brand
PEMAZYRE	PEMIGATINIB TAB 9 MG	21532260000330	Brand
PEMAZYRE	PEMIGATINIB TAB 13.5 MG	21532260000340	Brand

Approval Criteria

1 - Diagnosis of cholangiocarcinoma

AND

2 - Disease is one of the following:

Unresectable locally advanced

Metastatic

AND

3 - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [A]

AND

4 - Patient has been previously treated (e.g., chemotherapy)

Product Name:Pemazyre

Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PEMAZYRE	PEMIGATINIB TAB 4.5 MG	21532260000320	Brand
PEMAZYRE	PEMIGATINIB TAB 9 MG	21532260000330	Brand
PEMAZYRE	PEMIGATINIB TAB 13.5 MG	21532260000340	Brand

Approval Criteria

1 - Diagnosis of Myeloid/Lymphoid Neoplasms (MLNs)

AND

2 - Disease is relapsed or refractory

AND

3 - Disease has presence of fibroblast growth factor receptor 1 (FGFR1) rearrangement [B]

Product Name:Pemazyre	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PEMAZYRE	PEMIGATINIB TAB 4.5 MG	21532260000320	Brand
PEMAZYRE	PEMIGATINIB TAB 9 MG	21532260000330	Brand
PEMAZYRE	PEMIGATINIB TAB 13.5 MG	21532260000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Pemazyre	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PEMAZYRE	PEMIGATINIB TAB 4.5 MG	21532260000320	Brand
PEMAZYRE	PEMIGATINIB TAB 9 MG	21532260000330	Brand
PEMAZYRE	PEMIGATINIB TAB 13.5 MG	21532260000340	Brand

Approval Criteria

1 - Diagnosis of cholangiocarcinoma

AND

2 - Disease is one of the following:

Unresectable locally advanced

Metastatic

AND

3 - Submission of medical records (e.g., chart notes) confirming disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [A]

AND

4 - Patient has been previously treated (e.g., chemotherapy)

Product Name:Pemazyre	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PEMAZYRE	PEMIGATINIB TAB 4.5 MG	21532260000320	Brand
PEMAZYRE	PEMIGATINIB TAB 9 MG	21532260000330	Brand
PEMAZYRE	PEMIGATINIB TAB 13.5 MG	21532260000340	Brand

Approval Criteria

1 - Diagnosis of Myeloid/Lymphoid Neoplasms (MLNs)

AND

2 - Disease is relapsed or refractory

AND

3 - Submission of medical records (e.g., chart notes) confirming disease has presence of fibroblast growth factor receptor 1 (FGFR1) rearrangement [B]

3 . Endnotes

Per consultant feedback, rearrangement's are specific to FGFR2.

An FDA-approved test for detection of FGFR1 rearrangement in patients with relapsed or refractory myeloid/lymphoid neoplasm for selecting patients for treatment with Pemazyre is not available. However, MLNs with FGFR1 rearrangement can be confirmed with cytogenetic evaluation. [1]

4 . References

Pemazyre Prescribing Information. Incyte Corporation. Wilmington, DE. June 2023.

Prior Authorization Guideline

Guideline ID	GL-228513
Guideline Name	Phosphate Binders
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Fosrenol (lanthanum carbonate)
Hyperphosphatemia Indicated to reduce serum phosphate in patients with end-stage renal disease (ESRD).
Drug Name: Phoslyra (calcium acetate)
Hyperphosphatemia Indicated as an adjunct to reduction in dietary intake of phosphate and dialysis to reduce serum phosphorus in patients with kidney failure on dialysis.
Drug Name: Velphoro (sucroferric oxyhydroxide)
Hyperphosphatemia Indicated for the control of serum phosphorus levels in adult and pediatric patients 9 years of age and older with chronic kidney disease on dialysis.

2 . Criteria

Product Name:Velphoro	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
VELPHORO	SUCROFERRIC OXYHYDROXIDE CHEW TAB 500 MG	52800080100520	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of hyperphosphatemia in chronic kidney disease on dialysis

AND

1.2 One of the following:

1.2.1 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to two of the following:

calcium carbonate

calcium acetate

lanthanum carbonate

sevelamer carbonate

sevelamer HCl

Auryxia

OR

1.2.2 Patient is younger than or equal to 12 years of age

Product Name:Brand Fosrenol, Phoslyra	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
FOSRENOL	LANTHANUM CARBONATE CHEW TAB 500 MG (ELEMENTAL)	52800045200540	Brand
FOSRENOL	LANTHANUM CARBONATE CHEW TAB 750 MG (ELEMENTAL)	52800045200550	Brand
FOSRENOL	LANTHANUM CARBONATE CHEW TAB 1000 MG (ELEMENTAL)	52800045200560	Brand
FOSRENOL	LANTHANUM CARBONATE ORAL POWDER PACK 750 MG (ELEMENTAL)	52800045203030	Brand
FOSRENOL	LANTHANUM CARBONATE ORAL POWDER PACK 1000 MG (ELEMENTAL)	52800045203040	Brand
PHOSLYRA	CALCIUM ACETATE (PHOSPHATE BINDER) ORAL SOLN 667 MG/5ML	52800020102020	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 30-day supply, contraindication, or intolerance to two of the following:

calcium carbonate

calcium acetate

lanthanum carbonate

sevelamer carbonate

sevelamer HCl

3 . References

Velphoro Prescribing Information. Fresenius Medical Care North America. Waltham, MA. July 2024.

Fosrenol Prescribing Information. Takeda Pharmaceutical Company Limited. Lexington, MA. May 2020.

Phoslyra Prescribing Information. Layne Laboratories. Brockton, MA. September 2020.

Piqray (alpelisib)

Prior Authorization Guideline

Guideline ID	GL-228931
Guideline Name	Piqray (alpelisib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Piqray (alpelisib)
Advanced or Metastatic Breast Cancer Indicated in combination with fulvestrant for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

2 . Criteria

Product Name:Piqray	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PIQRAY 200MG DAILY DOSE	ALPELISIB TAB THERAPY PACK 200 MG DAILY DOSE	2153801000B720	Brand
PIQRAY 250MG DAILY DOSE	ALPELISIB TAB PACK 250 MG DAILY DOSE (200 MG & 50 MG TABS)	2153801000B725	Brand
PIQRAY 300MG DAILY DOSE	ALPELISIB TAB PACK 300 MG DAILY DOSE (2X150 MG TAB)	2153801000B730	Brand

Approval Criteria

1 - Diagnosis of advanced or metastatic breast cancer

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Used in combination with fulvestrant

AND

6 - Disease has progressed on or after an endocrine-based regimen

Product Name:Piqray	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PIQRAY 200MG DAILY DOSE	ALPELISIB TAB THERAPY PACK 200 MG DAILY DOSE	2153801000B720	Brand
PIQRAY 250MG DAILY DOSE	ALPELISIB TAB PACK 250 MG DAILY DOSE (200 MG & 50 MG TABS)	2153801000B725	Brand
PIQRAY 300MG DAILY DOSE	ALPELISIB TAB PACK 300 MG DAILY DOSE (2X150 MG TAB)	2153801000B730	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Piqray Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. January 2024.

4 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Pomalyst (pomalidomide)

Prior Authorization Guideline

Guideline ID	GL-228930
Guideline Name	Pomalyst (pomalidomide)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Pomalyst (pomalidomide)
Multiple myeloma Indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy. **Kaposi Sarcoma** Indicated for the treatment of: 1) Adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART). 2) Kaposi sarcoma (KS) in adult patients who are HIV-negative. Note: this indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name:Pomalyst	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
POMALYST	POMALIDOMIDE CAP 1 MG	21450080000110	Brand
POMALYST	POMALIDOMIDE CAP 2 MG	21450080000115	Brand
POMALYST	POMALIDOMIDE CAP 3 MG	21450080000120	Brand
POMALYST	POMALIDOMIDE CAP 4 MG	21450080000125	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

Product Name:Pomalyst	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
POMALYST	POMALIDOMIDE CAP 1 MG	21450080000110	Brand
POMALYST	POMALIDOMIDE CAP 2 MG	21450080000115	Brand
POMALYST	POMALIDOMIDE CAP 3 MG	21450080000120	Brand
POMALYST	POMALIDOMIDE CAP 4 MG	21450080000125	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of AIDS-related Kaposi sarcoma

OR

1.2 Both of the following:

1.2.1 Diagnosis of Kaposi sarcoma

AND

1.2.2 Patient is HIV-negative

Product Name:Pomalyst	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
POMALYST	POMALIDOMIDE CAP 1 MG	21450080000110	Brand
POMALYST	POMALIDOMIDE CAP 2 MG	21450080000115	Brand
POMALYST	POMALIDOMIDE CAP 3 MG	21450080000120	Brand
POMALYST	POMALIDOMIDE CAP 4 MG	21450080000125	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Pomalyst Prescribing Information, Celgene Corporation, Summit, NJ. March 2023.

National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 22, 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228707
Guideline Name	Pombiliti (cipaglucosidase alfa-atga)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Pombiliti (cipaglucosidase alfa-atga)
Late-Onset Pompe disease Indicated, in combination with Opfolda, an enzyme stabilizer, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

2 . Criteria

Product Name:Pombiliti	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
POMBILITI	CIPAGLUCOSIDASE ALFA-ATGA FOR IV SOLN 105 MG	30907730052120	Brand

Approval Criteria

1 - Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency)

AND

2 - Disease is confirmed by one of the following: [2, 4-5]

Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

Molecular genetic testing confirms mutations in the GAA gene

AND

3 - Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.) [A]

AND

4 - Medication is used in combination with Opfolda (miglustat)

AND

5 - Patient weight is greater than or equal to 40 kg

AND

6 - Trial and inadequate response to one of the following:

Lumizyme

Nexviazyme

AND

7 - Not to be used in combination with other miglustat products (i.e., Zavesca, Yargesa)

Product Name:Pombiliti	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
POMBILITI	CIPAGLUCOSIDASE ALFA-ATGA FOR IV SOLN 105 MG	30907730052120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in FVC, improvement in 6-minute walk distance [6MWD])

AND

2 - Medication is used in combination with Opfolda (miglustat)

AND

3 - Not to be used in combination with other miglustat products (i.e., Zavesca, Yargesa)

3 . Endnotes

Consensus recommendation based on current clinical guidelines indicate that treatment should be started in patients with late onset Pompe disease when they become symptomatic and/or show signs of disease progression [2, 4-5].

4 . References

Pombiliti Prescribing Information. Amicus Therapeutics US, LLC. Philadelphia, PA. Sept 2023.

Diaz, C., Diaz-Manera, J. Therapeutic Options for the Management of Pompe Disease: Current Challenges and Clinical Evidence in Therapeutics and Clinical Risk Management. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9759116/. Accessed November 2, 2023.

Cleveland Clinic - Pompe Disease. Available at: https://my.clevelandclinic.org/health/diseases/15808-pompe-disease. Accessed November 2, 2023.

Cupler, E., Berger, K., Leshner, R., et al. Consensus Treatment Recommendations for Late-Onset Pompe Disease. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3534745/. Accessed November 2, 2023.

Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Available at: https://www.orpha.net/data/patho/Cpg/en/PompeLateOnset_ES_en_CPG_ORPHA420429.pdf. Accessed November 2, 2023.

Prior Authorization Guideline

Guideline ID	GL-229145
Guideline Name	Prior Authorization Administrative Guideline
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/15/2011
P&T Revision Date:	10/16/2024

Note:

The purpose of this guideline is to establish policies and procedures on how to handle (1) formulary drugs with a prior authorization requirement that do not have official criteria posted or available, and (2) new FDA-approved indications, which are not addressed in the existing drug-specific prior authorization guideline. This guideline will not apply to drugs that are benefit exclusions, drugs with step therapy edits, drugs that require quantity limit review only, non-formulary drugs, or drugs that are not reviewed for prior authorization by OptumRx.

1 . Criteria

Product Name:Drugs with a prior authorization requirement for which a guideline is unavailable, OR new FDA-approved indications which are not addressed in the existing drug-specific prior authorization guideline	
Approval Length	12 month(s)

Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Prior Authorization			
Administrative			
Admin			
albenza			
albendazole			

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.2 Both of the following:

1.1.2.1 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

AND

1.1.2.2 Requested drug will be used at a dose which is within FDA recommendations

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Notes	This guideline should not be used to address step therapy.

2 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228515
Guideline Name	Procysbi (cysteamine bitartrate)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Procysbi (cysteamine bitartrate)
Nephropathic cystinosis Indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older.

2 . Criteria

Product Name:Procysbi Capsules, Procysbi Granules	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROCYSBI	CYSTEAMINE BITARTRATE DELAYED RELEASE GRANULES PACKET 75 MG	56400030103020	Brand
PROCYSBI	CYSTEAMINE BITARTRATE DELAYED RELEASE GRANULES PACKET 300 MG	56400030103040	Brand
PROCYSBI	CYSTEAMINE BITARTRATE CAP DELAYED RELEASE 25 MG (BASE EQUIV)	56400030106520	Brand
PROCYSBI	CYSTEAMINE BITARTRATE CAP DELAYED RELEASE 75 MG (BASE EQUIV)	56400030106530	Brand

Approval Criteria

1 - Diagnosis of nephropathic cystinosis

AND

2 - One of the following [A, 2, 3]:

2.1 Diagnosis is confirmed by elevated leukocyte cystine levels (LCL)

OR

2.2 Diagnosis is confirmed by genetic analysis of the CTNS gene

OR

2.3 Diagnosis is confirmed by demonstration of cysteine corneal crystals by slit lamp examination

AND

3 - Trial and failure or intolerance to Cystagon (immediate-release cysteamine bitartrate)

AND

4 - Patient is 1 year of age or older

Product Name:Procysbi Capsules, Procysbi Granules	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROCYSBI	CYSTEAMINE BITARTRATE DELAYED RELEASE GRANULES PACKET 75 MG	56400030103020	Brand
PROCYSBI	CYSTEAMINE BITARTRATE DELAYED RELEASE GRANULES PACKET 300 MG	56400030103040	Brand
PROCYSBI	CYSTEAMINE BITARTRATE CAP DELAYED RELEASE 25 MG (BASE EQUIV)	56400030106520	Brand
PROCYSBI	CYSTEAMINE BITARTRATE CAP DELAYED RELEASE 75 MG (BASE EQUIV)	56400030106530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decrease in cystine levels in white blood cells)

3 . Endnotes

A definitive diagnosis can be verified by measuring leukocyte cystine levels, genetic analysis of the CTNS gene or demonstration of corneal crystals by slit lamp examination. [2-3]

4 . References

Procysbi Prescribing Information. Horizon Pharma USA, Inc. Lake Forest, IL. February 2022.

Emma F, Nesterova G, Langman C, et al. Nephropathic cystinosis: an international consensus document. Nephrol Dial Transplant. 2014 Sep;29(Suppl 4): iv87–iv94.

Wilmer MJ, Schoeber JP, van den Heuvel LP, Levtchenko EN. Cystinosis: practical tools for diagnosis and treatment [educational review]. Pediatr Nephrol 2011 Feb; 26(2): 205-15.

Prior Authorization Guideline

Guideline ID	GL-228934
Guideline Name	Prolia (denosumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Prolia (denosumab)
Treatment of postmenopausal women with osteoporosis at high risk for fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures. **Treatment to increase bone mass in men with osteoporosis at high risk for fracture** Indicated for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. **Treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer [A]** Indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures. NOTE: The use of Prolia for the treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer should not be confused with the use of Xgeva (another

injectable formulation of denosumab) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors (including breast cancer and prostate cancer).

Treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer [B] Indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. NOTE: The use of Prolia for the treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer should not be confused with the use of Xgeva (another injectable formulation of denosumab) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors (including breast cancer and prostate cancer).

Treatment of Glucocorticoid-Induced Osteoporosis Indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name:Prolia	
Diagnosis	Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
Approval Length	12 months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Diagnosis of nonmetastatic prostate cancer

AND

2 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]

2.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]

OR

2.2 Bilateral orchiectomy (i.e., surgical castration)

AND

3 - One of the following:

3.1 Age greater than or equal to 70 years [11,C]

OR

3.2 Both of the following:

3.2.1 Age less than 70 years [11]

AND

3.2.2 One of the following:

3.2.2.1 Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) [11]

OR

3.2.2.2 History of one of the following resulting from minimal trauma: [9,11]

Vertebral compression fracture

Fracture of the hip

Fracture of the distal radius

Fracture of the pelvis

Fracture of the proximal humerus

AND

4 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., zoledronic acid) [19]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Prolia	
Diagnosis	Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
Approval Length	12 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]

1.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]

OR

1.2 Bilateral orchiectomy (i.e., surgical castration)

AND

2 - No evidence of metastases

AND

3 - Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Prolia	
Diagnosis	Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
Approval Length	12 months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12,B]

AND

3 - One of the following:

3.1 Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) [12,E]

OR

3.2 History of one of the following resulting from minimal trauma: [9]

Vertebral compression fracture

Fracture of the hip

Fracture of the distal radius

Fracture of the pelvis

Fracture of the proximal humerus

AND

4 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate) [20]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Prolia	
Diagnosis	Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
Approval Length	12 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12]

AND

2 - Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Prolia	
Diagnosis	Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	30044530000E520	Brand

Approval Criteria

1 - Diagnosis of postmenopausal osteoporosis or osteopenia [2,5]

AND

2 - One of the following: [5,17]

2.1 Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

2.2 Both of the following:

2.2.1 BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions

Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

2.3 History of one of the following resulting from minimal trauma:

Vertebral compression fracture

Fracture of the hip

Fracture of the distal radius

Fracture of the pelvis

Fracture of the proximal humerus

AND

3 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Prolia	
Diagnosis	Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture
Approval Length	24 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Prolia	
Diagnosis	Increase bone mass in men at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient is a male with osteoporosis or osteopenia

AND

2 - One of the following: [16,17]

2.1 Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

2.2 Both of the following:

2.2.1 BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions

Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

2.3 History of one of the following resulting from minimal trauma:

Vertebral compression fracture

Fracture of the hip

Fracture of the distal radius

Fracture of the pelvis

Fracture of the proximal humerus

AND

3 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Prolia	
Diagnosis	Increase bone mass in men at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Prolia	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - Patient is initiating or continuing on greater than or equal to 7.5 mg/day of prednisone (or its equivalent) and is expected to remain on glucocorticoid therapy for at least 6 months

AND

3 - One of the following: [F]

3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions

Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

Vertebral compression fracture

Fracture of the hip

Fracture of the distal radius

Fracture of the pelvis

Fracture of the proximal humerus

OR

3.4 One of the following:

Glucocorticoid dosing of at least 30 mg per day

Cumulative glucocorticoid dosing of at least 5 grams per year

AND

4 - Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [G]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Prolia	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Notes	If patient meets criteria above, please approve at GPI-12.

3 . Definitions

Definition	Description
Bone mineral density (BMD) [3]	A risk factor for fractures. By DXA, BMD is expressed as the amount of mineralized tissue in the area scanned (g/cm2); with QCT, BMD is expressed as the amount per volume of bone (mg/cm3). Hip BMD

	by DXA is considered the best predictor of hip fracture; it appears to predict other types of fractures as well as measurements made at other skeletal sites. Lumbar spine BMD may be preferable to assess changes early in menopause and after bilateral ovariectomy and may be better than hip BMD in predicting risk of spine fractures especially in women in their 50s and 60s.
Dual x-ray absorptiometry (DXA) [3]	A diagnostic test used to assess bone density at various skeletal sites using radiation exposure about one-tenth that of a standard chest X-ray. Central DXA (lumbar spine, hip) is the preferred measurement for definitive diagnosis of osteoporosis and for monitoring the effects of therapy.
Fracture [3]	Breakage of a bone, either complete or incomplete whether from trauma, repetitive stress, or bone insufficiency. Osteoporosis can contribute to any fracture at any skeletal site, but overwhelmingly affects sites that predominate in trabecular bone: femoral neck, total hip, spine, and forearm. Fractures in cortical bone dense sites are less likely to be attributed to osteoporosis, such as fingers, toes, skull, and face. Vertebral compression fractures are the most common type of osteoporotic fracture.
Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean BMD of a young adult reference population (T-score between − 1.0 and − 2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration of bone tissue, decreased bone strength, bone fragility, and a consequent increase in fracture risk; BMD 2.5 or more standard deviations below the mean BMD of a young adult reference population (T-score at or below − 2.5).
Peripheral DXA [3]	A DXA test used to assess bone density in the forearm, finger, and heel.
Quantitative computed tomography (QCT) [3]	A diagnostic test used to assess volumetric bone density; reflects three-dimensional BMD. Usually used to assess the lumbar spine but has been adapted for other skeletal sites (e.g., hip). It is also possible to measure trabecular and cortical bone density in the periphery by peripheral QCT (pQCT) or high-resolution pQCT (HRpQCT).
Quantitative ultrasound densitometry (QUS) [3]	A diagnostic test used to assess bone density at the calcaneus or tibia. Ultrasound measurements correlate only modestly with other assessments of bone density in the same patient, yet some

	prospective studies indicate that ultrasound may predict fractures as effectively as other measures of bone density.
Remodeling [3]	Also called bone turnover, remodeling is the process by which the skeleton repairs damage and maintains serum calcium levels through the ongoing lifelong dual processes of bone resorption (breakdown) and formation
Resorption [3]	The breakdown and removal of bone tissue during bone remodeling.
Risk factors [3]	For osteoporotic fractures, risk factors include low BMD, parental history of hip fracture, low body weight, previous fracture, smoking, excess alcohol intake, glucocorticoid use, secondary causes of osteoporosis (e.g., rheumatoid arthritis), and history of falls. These readily accessible and commonplace factors are associated with the risk of hip fracture and, in most cases, with that of vertebral and other types of fracture as well.
Severe or “established” osteoporosis [3]	Osteoporosis characterized by bone density that is 2.5 standard deviations or more below the young normal mean (T-score at or below -2.5), accompanied by the occurrence of at least one fragility-related fracture.
T-score [3]	In describing BMD, the number of standard deviations above or below the mean BMD of a young adult reference population.
Z-score [3]	In describing BMD, the number of standard deviations above or below the mean BMD for persons of the same age, sex, and ethnicity.

4 . Endnotes

Androgen deprivation therapy (ADT) is commonly used in the treatment of prostate cancer. ADT can be accomplished using luteinizing hormone-releasing hormone (LHRH) agonists (medical castration), also known as gonadotropin releasing hormone (GnRH) agonists, or bilateral orchiectomy (surgical castration), which are equally effective. [13] Examples of LHRH agonists include Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin).

Aromatase inhibitors (AIs) include selective, nonsteroidal AIs (Arimidex [anastrozole] and Femara [letrozole]) and steroidal AIs (Aromasin [exemestane]).

Meta-analyses have shown that advancing age increases fracture risk beyond that predicted by age related loss of BMD. Although typical changes in BMD would predict a 4-fold increase in fracture risk from ages 50 to 90 years, fracture risk actually increases 30-

fold. Estimated fracture rates using FRAX calculations reflect a strong influence of older age on risk for clinical fracture. When clinical factors were used without BMD in one cross-sectional study, FRAX estimated that 76.6% of men in their 70s and virtually all men 80 years old or older exceeded the NOF recommended risk threshold for drug therapy. [14]

Most men run a 2-year course of androgen deprivation therapy while most women receive treatment with aromatase inhibitors for about 5 years. A one year treatment authorization is reasonable. [15]

Owing to the rate of bone loss associated with breast cancer treatments (i.e., aromatase inhibitors), and uncertainties about the interaction between aromatase inhibitor use and BMD for fracture risk, the threshold for intervention has been set at a higher level than that generally recommended for postmenopausal osteoporosis. [8]

According to the American College of Rheumatology (ACR) guidelines for the prevention and treatment of glucocorticoid-induced osteoperosis, patients considered at high risk of fractures are as follows: (a) prior osteoporotic fracture, (b) a hip or spine BMD T-score less than or equal to -2.5, or (c) FRAX 10-year risk of hip or major osteoporotic fracture at 3 percent or more and 20 percent or more, respectively. [18]

According to ACR, oral bisphosphonates are considered first-line for patients with glucocorticod-induced osteoperosis at high risk for fractures. For patients in whom oral bisphosphonates are not appropriate, IV bisphosphonates should be considered. [18]

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6 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228937
Guideline Name	Promacta (eltrombopag)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Promacta (eltrombopag)
Treatment of Thrombocytopenia in Patients with Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. **Treatment of Thrombocytopenia in Patients with Hepatitis C Infection** Indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Promacta should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. Limitations of use: • Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection. **Treatment of Severe Aplastic Anemia** Indicated in combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years

and older with severe aplastic anemia. Indicated for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

2 . Criteria

Product Name:Promacta	
Diagnosis	Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	

Approval Criteria

1 - Diagnosis of one of the following:

Persistent ITP

Chronic ITP

Relapsed/refractory ITP [8]

AND

2 - Baseline platelet count is less than 30,000/mcL [2, 3, 8]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [2, 3, 8]

Corticosteroids

Immunoglobulins

Splenectomy

AND

4 - Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Promacta	
Diagnosis	Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand

PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to Promacta therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding

Product Name:Promacta	
Diagnosis	First-Line for Severe Aplastic Anemia
Approval Length	6 Months [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand

Approval Criteria

1 - Diagnosis of severe aplastic anemia

AND

2 - Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy with any equine antithymocyte globulin plus cyclosporine, alemtuzumab, or high dose cyclophosphamide) [1]

AND

3 - Patient meets at least TWO of the following [9, 10]:

Absolute neutrophil count < 500/mcL

Platelet count < 20,000/mcL

Absolute reticulocyte count < 60,000/mcL

AND

4 - Used in combination with standard immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine] and cyclosporine) [1]

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Promacta	
Diagnosis	Refractory Severe Aplastic Anemia
Approval Length	16 weeks [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand

Approval Criteria

1 - Diagnosis of refractory severe aplastic anemia

AND

2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy with antithymocyte globulin (ATG) and cyclosporine [5-7]

AND

3 - Patient has thrombocytopenia defined as platelet count less than 30,000/mcL

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Promacta	
Diagnosis	Refractory Severe Aplastic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to Promacta therapy as evidenced by an increase in platelet count

Product Name:Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C-associated thrombocytopenia

AND

2 - One of the following:

2.1 Planning to initiate and maintain interferon-based treatment [1]

OR

2.2 Currently receiving interferon-based treatment

AND

3 - Prescribed by or in consultation with one of the following:

Hematologist/oncologist

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

Product Name:Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQUIV)	82405030103020	Brand

Approval Criteria

1 - One of the following:

1.1 For patients that started treatment with Promacta prior to initiation of treatment with interferon, Promacta will be approved when both of the following criteria are met:

1.1.1 Currently on antiviral interferon therapy for treatment of chronic hepatitis C [1]

AND

1.1.2 Documentation that the patient reached a threshold platelet count that allows initiation of antiviral interferon therapy with Promacta treatment by week 9 [C]

OR

1.2 For patients that started treatment with Promacta while on concomitant treatment with interferon, Promacta will be approved based on the following criterion:

1.2.1 Currently on antiviral interferon therapy for treatment of chronic hepatitis C

3 . Endnotes

The prescribing information states that the total duration of Promacta treatment for first-line severe aplastic anemia is 6 months. [1]

In patients with severe aplastic anemia, hematologic response requires dose titration, generally up to 150 mg, and may take up to 16 weeks after starting Promacta. The dose should be adjusted every 2 weeks as necessary to achieve the target platelet count greater than or equal to 50 x 10^9/L. If no hematologic response has occurred after 16 weeks of therapy with Promacta, therapy should be discontinued. [1]

Promacta was studied in two phase 3 trials for chronic hepatitis C-associated thrombocytopenia in two periods. Patients received Promacta in the first period for a maximum of 9 weeks in order to achieve a pre-specified threshold platelet count (greater than or equal to 90 x 10^9/L for Trial 1 and greater than or equal to 100 x 10^9/L for Trial 2); if the pre-specified threshold platelet count was reached, initiation of antiviral therapy in combination with interferon and ribavirin was administered for up to 48 weeks in the second period. The lowest dose of Promacta should be used to achieve and maintain a platelet count necessary to initiate and maintain interferon-based therapy. Dose adjustments are based upon the platelet count response. [1]

4 . References

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Per clinical consult with hematologist/oncologist. January 24, 2019.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233320
Guideline Name	Proton Pump Inhibitors
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/17/2025

1 . Indications

Drug Name: Aciphex (rabeprazole)
Healing of Erosive or Ulcerative GERD in Adults Indicated for short-term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative GERD. For those patients who have not healed after 8 weeks of treatment, an additional 8-week course of Aciphex may be considered. **Maintenance of Healing of Erosive or Ulcerative GERD in Adults** Indicated for maintaining healing and reduction in relapse rates of heartburn symptoms in patients with erosive or ulcerative gastroesophageal reflux disease (GERD Maintenance). Controlled studies do not extend beyond 12 months. **Treatment of Symptomatic Gastroesophageal Reflux Disease (GERD) in Adults** Indicated for the treatment of daytime and nighttime heartburn and other symptoms associated with GERD in adults for up to 4 weeks. **Healing of Duodenal Ulcers in Adults** Indicated for short-term (up to 4 weeks) treatment in the healing and symptomatic relief of duodenal ulcers. Most patients heal within 4 weeks. **Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence in**

Adults In combination with amoxicillin and clarithromycin as a three drug regimen, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history within the past 5 years) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Pathological Hypersecretory Conditions including Zollinger-Ellison Syndrome in Adults Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

Short-term Treatment of Symptomatic GERD in Adolescent Patients 12 years of Age and Older Indicated for the treatment of symptomatic GERD in adolescents 12 years of age and above for up to 8 weeks.

Drug Name: Aciphex Sprinkle (rabeprazole)

Patients 1 to 11 Years of Age Indicated for treatment of GERD in pediatric patients 1 to 11 years of age for up to 12 weeks.

Drug Name: Dexilant (dexlansoprazole)

Healing of Erosive Esophagitis Indicated in patients 12 years of age and older for healing of all grades of erosive esophagitis for up to 8 weeks.

Maintenance of Healed Erosive Esophagitis Indicated in patients 12 years of age and older to maintain healing of erosive esophagitis and relief of heartburn for up to six months in adults and 16 weeks in patients 12 to 17 years of age.

Symptomatic Non-Erosive GERD Indicated in patients 12 years of age and older for the treatment of heartburn associated with symptomatic non-erosive GERD for 4 weeks.

Drug Name: Konvomep (omeprazole and sodium bicarbonate)

Gastric Ulcer Indicated for the short-term treatment (4 to 8 weeks) of active benign gastric ulcer in adults.

Reduction of Risk of Upper Gastrointestinal Bleeding in Critically Ill Patients Indicated for the reduction of risk of upper gastrointestinal (GI) bleeding in critically ill adult patients.

Drug Name: Nexium (esomeprazole)

Healing of Erosive Esophagitis Nexium delayed-release capsules and Nexium delayed-release oral suspension are indicated for the short-term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis in adults. For those patients who have not healed after 4 to 8 weeks of treatment, an additional 4 to 8 week course of Nexium may be considered. In pediatric patients 1 month to less than 1 year of age, Nexium delayed-release oral suspension is indicated for short-term treatment (up to 6 weeks) of erosive esophagitis due to acid-medicated GERD. In pediatric patients 1 year to 11 years of age, Nexium delayed-release oral suspension is indicated for the short-term

treatment (8 weeks) for the healing of EE. In pediatric patients 12 years to 17 years of age, Nexium delayed-release capsules and Nexium delayed-release oral suspension are indicated for for the short-term treatment (4 to 8 weeks) for the healing of EE.

Maintenance of Healing of Erosive Esophagitis NEXIUM delayed-release capsules and NEXIUM for delayed-release oral suspension are indicated for the maintenance of healing of erosive esophagitis in adults. Controlled studies do not extend beyond 6 months.

Symptomatic GERD NEXIUM delayed-release capsules and NEXIUM for delayed-release oral suspension are indicated for short-term treatment (4 to 8 weeks) of heartburn and other symptoms associated with GERD in adults. NEXIUM delayed-release capsules and NEXIUM for delayed-release oral suspension are indicated for short-term treatment (4 weeks) of heartburn and other symptoms associated with GERD in pediatric patients 12 years to 17 years of age. NEXIUM for delayed-release oral suspension is indicated for short-term treatment (up to 8 weeks) of heartburn and other symptoms associated with GERD in pediatric patients 1 year to 11 years of age.

Risk Reduction of NSAID-Associated Gastric Ulcer NEXIUM delayed-release capsules and NEXIUM for delayed-release oral suspension are indicated for the reduction in the occurrence of gastric ulcers associated with continuous NSAID therapy in adult patients at risk for developing gastric ulcers. Patients are considered to be at risk due to their age (60 years and older) and/or documented history of gastric ulcers. Controlled studies do not extend beyond 6 months.

Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. Triple therapy: NEXIUM delayed-release capsules or NEXIUM for delayed-release oral suspension in combination with amoxicillin and clarithromycin is indicated for the treatment of adult patients with H. pylori infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate H. pylori. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Pathological Hypersecretory Conditions including Zollinger-Ellison Syndrome NEXIUM delayed-release capsules and NEXIUM for delayed-release oral suspension are indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome, in adults.

Drug Name: Prevacid (lansoprazole)

Treatment of Active Duodenal Ulcer Indicated for short-term treatment (for 4 weeks) for healing and symptom relief of active duodenal ulcer in adults.

Eradication of H. pylori to Reduce the Risk of Duodenal Ulcer Recurrence In combination with amoxicillin plus clarithromycin as triple therapy, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. In combination with amoxicillin as dual therapy, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) who are either allergic or intolerant to clarithromycin or in

whom resistance to clarithromycin is known or suspected. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

Maintenance of Healed Duodenal Ulcers Indicated to maintain healing of duodenal ulcers in adults. Controlled studies do not extend beyond 12 months.

Treatment of Active Benign Gastric Ulcer Indicated for short-term treatment (up to 8 weeks) for healing and symptom relief of active benign gastric ulcer in adults.

Healing of NSAID-Associated Gastric Ulcer Indicated in adults for the treatment of NSAID-associated gastric ulcer in patients who continue NSAID use. Controlled studies did not extend beyond 8 weeks.

Risk Reduction of NSAID-Associated Gastric Ulcer Indicated in adults for reducing the risk of NSAID-associated gastric ulcers in patients with a history of a documented gastric ulcer who require the use of an NSAID. Controlled studies did not extend beyond 12 weeks.

Treatment of Symptomatic GERD Indicated for short-term treatment in adults and pediatric patients 12 to 17 years of age (up to eight weeks) and pediatric patients one to 11 years of age (up to 12 weeks) for the treatment of heartburn and other symptoms associated with GERD.

Treatment of Erosive Esophagitis Indicated for short-term treatment in adults and pediatric patients 12 to 17 years of age (up to eight weeks) and pediatric patients one to 11 years of age (up to 12 weeks) for healing and symptom relief of all grades of erosive esophagitis. For adults who do not heal with Prevacid for 8 weeks (5 to 10%), it may be helpful to give an additional 8 weeks of treatment. If there is a recurrence of erosive esophagitis, an additional 8-week course of Prevacid may be considered.

Maintenance of Healing of Erosive Esophagitis Indicated in adults to maintain healing of EE. Controlled studies did not extend beyond 12 months.

Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome Indicated in adults for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

Drug Name: Prilosec (omeprazole)

Treatment of Active Duodenal Ulcer Indicated for short-term treatment of active duodenal ulcer in adults. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence In combination with clarithromycin and amoxicillin, indicated for treatment of patients with H. pylori infection and duodenal ulcer disease (active or up to 1-year history) to eradicate H. pylori in adults. In combination with clarithromycin, indicated for treatment of patients with H. pylori infection and duodenal ulcer disease to eradicate H. pylori in adults. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. Among patients who fail therapy, Prilosec with clarithromycin is more likely to be associated with the development of clarithromycin resistance as compared with triple therapy. In patients who fail therapy,

susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Treatment of Active Benign Gastric Ulcer Indicated for short-term treatment (4 to 8 weeks) of active benign gastric ulcer in adults.

Treatment of Symptomatic GERD Indicated for the treatment of heartburn and other symptoms associated with GERD for up to 4 weeks in patients 1 year of age and older.

Treatment of Erosive Esophagitis (EE) Due to Acid-Mediated GERD Indicated for the short-term treatment (4 to 8 weeks) of erosive esophagitis due to acid-mediated GERD that has been diagnosed by endoscopy in patients 1 year of age and older. The efficacy of Prilosec used for longer than 8 weeks in these patients has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of erosive esophagitis or GERD symptoms, additional 4 to 8 week courses of omeprazole may be considered. Also indicated for the short-term treatment (up to 6 weeks) of erosive esophagitis due to acid-mediated GERD in pediatric patients 1 month to less than 1 year of age.

Maintenance of Healing of Erosive Esophagitis Due to Acid-Mediated GERD Indicated for the maintenance healing of EE due to acid-mediated GERD in patients 1 year of age and older. Controlled studies do not extend beyond 12 months.

Pathological Hypersecretory Conditions Indicated for the long-term treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple endocrine adenomas and systemic mastocytosis) in adults.

Drug Name: Protonix (pantoprazole)

Short-Term Treatment of Erosive Esophagitis Associated With GERD Indicated in adults and pediatric patients five years of age and older for the short-term treatment (up to 8 weeks) in the healing and symptomatic relief of erosive esophagitis. For those adult patients who have not healed after 8 weeks of treatment, an additional 8-week course of Protonix may be considered. Safety of treatment beyond 8 weeks in pediatric patients has not been established.

Maintenance of Healing of Erosive Esophagitis Indicated for maintenance of healing of erosive esophagitis and reduction in relapse rates of daytime and nighttime heartburn symptoms in adult patients with GERD. Controlled studies did not extend beyond 12 months.

Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

Drug Name: Zegerid (omeprazole/sodium bicarbonate)

Duodenal Ulcer Indicated for short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Gastric Ulcer Indicated for short-term treatment (4-8 weeks) of active benign gastric ulcer.

Symptomatic GERD Indicated for the treatment of heartburn and other symptoms associated with GERD for up to 4 weeks.

Erosive Esophagitis due to acid-mediated GERD Indicated for the short-term treatment (4 to 8 weeks) of erosive esophagitis due to acid-mediated GERD which has been diagnosed by endoscopy in adults. The efficacy of ZEGERID used for longer than 8 weeks in patients with EE has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of EE or GERD symptoms (e.g., heartburn), additional 4 to 8-week courses of ZEGERID may be considered.

Maintenance of Healing of Erosive Esophagitis Due to Acid-Mediated GERD Indicated to maintain healing of erosive esophagitis due to acid-mediated GERD. Controlled studies do not extend beyond 12 months.

Reduction of Risk of Upper Gastrointestinal Bleeding in Critically Ill Patients (40 mg oral suspension only) Indicated for the reduction of risk of upper GI bleeding in critically ill patients.

2 . Criteria

Product Name:Brand Aciphex tablets, Authorized Brand Alternative Rabeprazole Sprinkle, Brand Dexilant capsules, Brand Prevacid capsules, Brand Prevacid Solutab, Prilosec suspension, Brand Protonix tablets, Brand Protonix suspension, Brand Zegerid capsules, Brand Zegerid suspension, First-Lansoprazole suspension, First-Omeprazole suspension, Konvomep suspension, First Pantoprazole

Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
FIRST-LANSOPRAZOLE	LANSOPRAZOLE SUSP 3 MG/ML (COMPOUND KIT)	49270040001820	Brand
PREVACID	LANSOPRAZOLE CAP DELAYED RELEASE 15 MG	49270040006510	Brand
PREVACID	LANSOPRAZOLE CAP DELAYED RELEASE 30 MG	49270040006520	Brand
FIRST-OMEPRAZOLE	OMEPRAZOLE SUSP 2 MG/ML (COMPOUND KIT)	49270060001820	Brand
PROTONIX	PANTOPRAZOLE SODIUM EC TAB 20 MG (BASE EQUIV)	49270070100610	Brand
PROTONIX	PANTOPRAZOLE SODIUM EC TAB 40 MG (BASE EQUIV)	49270070100620	Brand

ZEGERID	OMEPRAZOLE-SODIUM BICARBONATE CAP 20-1100 MG	49996002600120	Brand
ZEGERID	OMEPRAZOLE-SODIUM BICARBONATE CAP 40-1100 MG	49996002600140	Brand
ZEGERID	OMEPRAZOLE-SODIUM BICARBONATE POWD PACK FOR SUSP 20-1680 MG	49996002603020	Brand
ZEGERID	OMEPRAZOLE-SODIUM BICARBONATE POWD PACK FOR SUSP 40-1680 MG	49996002603040	Brand
PROTONIX	PANTOPRAZOLE SODIUM FOR DELAYED RELEASE SUSP PACKET 40 MG	49270070103020	Brand
RABEPRAZOLE SODIUM DR SPRINKLE	RABEPRAZOLE SODIUM CAPSULE SPRINKLE DR 10 MG	49270076106810	Generic
PREVACID SOLUTAB	LANSOPRAZOLE TAB DELAYED RELEASE ORALLY DISINTEGRATING 15 MG	4927004000H315	Brand
PREVACID SOLUTAB	LANSOPRAZOLE TAB DELAYED RELEASE ORALLY DISINTEGRATING 30 MG	4927004000H330	Brand
ACIPHEX	RABEPRAZOLE SODIUM EC TAB 20 MG	49270076100620	Brand
KONVOMEP	OMEPRAZOLE-SODIUM BICARBONATE FOR ORAL SUSP 2-84 MG/ML	49996002601920	Brand
DEXILANT	DEXLANSOPRAZOLE CAP DELAYED RELEASE 30 MG	49270020006520	Brand
DEXILANT	DEXLANSOPRAZOLE CAP DELAYED RELEASE 60 MG	49270020006530	Brand
FIRST PANTOPRAZOLE	*PANTOPRAZOLE SODIUM SUSP 4 MG/ML (COMPOUND KIT)**	49270070101820	Brand
PRILOSEC	OMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 2.5 MG	49270060103020	Brand
PRILOSEC	OMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 10 MG	49270060103030	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure or intolerance to at least two of the following:

dexlansoprazole

esomeprazole

omeprazole

lansoprazole (capsule)

pantoprazole

rabeprazole (tablets)

Product Name:Brand Aciphex tablets*, Authorized Brand Alternative Rabeprazole Sprinkle*, Generic rabeprazole tablets, Brand Dexilant capsules, Brand Nexium capsules, Generic esomeprazole capsules, Nexium suspension, Brand Prevacid capsules*, Generic lansoprazole capsules, Brand Prevacid Solutab*, Generic lansoprazole orally disintegrating tablets, Generic omeprazole capsules, Prilosec suspension*, Brand Protonix tablets*, Generic pantoprazole tablets, Brand Protonix suspension*, Generic pantoprazole suspension, Brand Zegerid capsules*, Generic omeprazole-sodium bicarbonate capsules, Brand Zegerid suspension*, Generic omeprazole-sodium bicarbonate suspension, Generic dexlansoprazole capsules

Diagnosis	Twice-daily (BID) PPI Therapy**
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
FIRST-LANSOPRAZOLE	LANSOPRAZOLE SUSP 3 MG/ML (COMPOUND KIT)	49270040001820	Brand
PREVACID	LANSOPRAZOLE CAP DELAYED RELEASE 15 MG	49270040006510	Brand
PREVACID	LANSOPRAZOLE CAP DELAYED RELEASE 30 MG	49270040006520	Brand
FIRST-OMEPRAZOLE	OMEPRAZOLE SUSP 2 MG/ML (COMPOUND KIT)	49270060001820	Brand
PROTONIX	PANTOPRAZOLE SODIUM EC TAB 20 MG (BASE EQUIV)	49270070100610	Brand
PROTONIX	PANTOPRAZOLE SODIUM EC TAB 40 MG (BASE EQUIV)	49270070100620	Brand
OMEPRAZOLE/SODIUM BICARBONATE	OMEPRAZOLE-SODIUM BICARBONATE CAP 20-1100 MG	49996002600120	Generic
ZEGERID	OMEPRAZOLE-SODIUM BICARBONATE CAP 20-1100 MG	49996002600120	Brand
ZEGERID	OMEPRAZOLE-SODIUM BICARBONATE CAP 40-1100 MG	49996002600140	Brand
OMEPRAZOLE/SODIUM BICARBONATE	OMEPRAZOLE-SODIUM BICARBONATE CAP 40-1100 MG	49996002600140	Generic

ZEGERID	OMEPRAZOLE-SODIUM BICARBONATE POWD PACK FOR SUSP 20-1680 MG	49996002603020	Brand
ZEGERID	OMEPRAZOLE-SODIUM BICARBONATE POWD PACK FOR SUSP 40-1680 MG	49996002603040	Brand
PROTONIX	PANTOPRAZOLE SODIUM FOR DELAYED RELEASE SUSP PACKET 40 MG	49270070103020	Brand
NEXIUM	ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 40 MG	49270025103040	Brand
NEXIUM	ESOMEPRAZOLE MAGNESIUM CAP DELAYED RELEASE 20 MG	49270025106520	Brand
NEXIUM	ESOMEPRAZOLE MAGNESIUM CAP DELAYED RELEASE 40 MG	49270025106540	Brand
LANSOPRAZOLE	LANSOPRAZOLE CAP DELAYED RELEASE 15 MG	49270040006510	Generic
LANSOPRAZOLE	LANSOPRAZOLE CAP DELAYED RELEASE 30 MG	49270040006520	Generic
OMEPRAZOLE	OMEPRAZOLE CAP DELAYED RELEASE 10 MG	49270060006510	Generic
OMEPRAZOLE	OMEPRAZOLE CAP DELAYED RELEASE 20 MG	49270060006520	Generic
OMEPRAZOLE	OMEPRAZOLE CAP DELAYED RELEASE 40 MG	49270060006530	Generic
PANTOPRAZOLE SODIUM	PANTOPRAZOLE SODIUM EC TAB 20 MG (BASE EQUIV)	49270070100610	Generic
PANTOPRAZOLE SODIUM	PANTOPRAZOLE SODIUM EC TAB 40 MG (BASE EQUIV)	49270070100620	Generic
DEXILANT	DEXLANSOPRAZOLE CAP DELAYED RELEASE 30 MG	49270020006520	Brand
DEXILANT	DEXLANSOPRAZOLE CAP DELAYED RELEASE 60 MG	49270020006530	Brand
NEXIUM	ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACK 2.5 MG	49270025103004	Brand
NEXIUM	ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 5 MG	49270025103007	Brand
NEXIUM	ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 10 MG	49270025103010	Brand
NEXIUM	ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 20 MG	49270025103020	Brand
RABEPRAZOLE SODIUM	RABEPRAZOLE SODIUM EC TAB 20 MG	49270076100620	Generic
OMEPRAZOLE/SODIUM BICARBONATE	OMEPRAZOLE-SODIUM BICARBONATE POWD PACK FOR SUSP 20-1680 MG	49996002603020	Generic

OMEPRAZOLE/SODIUM BICARBONATE	OMEPRAZOLE-SODIUM BICARBONATE POWD PACK FOR SUSP 40-1680 MG	49996002603040	Generic
ESOMEPRAZOLE MAGNESIUM	ESOMEPRAZOLE MAGNESIUM CAP DELAYED RELEASE 20 MG (BASE EQ)	49270025106520	Generic
ESOMEPRAZOLE MAGNESIUM	ESOMEPRAZOLE MAGNESIUM CAP DELAYED RELEASE 40 MG (BASE EQ)	49270025106540	Generic
RABEPRAZOLE SODIUM DR SPRINKLE	RABEPRAZOLE SODIUM CAPSULE SPRINKLE DR 10 MG	49270076106810	Generic
PREVACID SOLUTAB	LANSOPRAZOLE TAB DELAYED RELEASE ORALLY DISINTEGRATING 15 MG	4927004000H315	Brand
PREVACID SOLUTAB	LANSOPRAZOLE TAB DELAYED RELEASE ORALLY DISINTEGRATING 30 MG	4927004000H330	Brand
LANSOPRAZOLE ODT	LANSOPRAZOLE TAB DELAYED RELEASE ORALLY DISINTEGRATING 15 MG	4927004000H315	Generic
LANSOPRAZOLE ODT	LANSOPRAZOLE TAB DELAYED RELEASE ORALLY DISINTEGRATING 30 MG	4927004000H330	Generic
LANSOPRAZOLE	LANSOPRAZOLE TAB DELAYED RELEASE ORALLY DISINTEGRATING 15 MG	4927004000H315	Generic
LANSOPRAZOLE	LANSOPRAZOLE TAB DELAYED RELEASE ORALLY DISINTEGRATING 30 MG	4927004000H330	Generic
ACIPHEX	RABEPRAZOLE SODIUM EC TAB 20 MG	49270076100620	Brand
PANTOPRAZOLE SODIUM	PANTOPRAZOLE SODIUM FOR DELAYED RELEASE SUSP PACKET 40 MG	49270070103020	Generic
DEXLANSOPRAZOLE	DEXLANSOPRAZOLE CAP DELAYED RELEASE 60 MG	49270020006530	Generic
DEXLANSOPRAZOLE	DEXLANSOPRAZOLE CAP DELAYED RELEASE 30 MG	49270020006520	Generic
DEXILANT	DEXLANSOPRAZOLE CAP DELAYED RELEASE 30 MG	49270020006520	Brand
DEXILANT	DEXLANSOPRAZOLE CAP DELAYED RELEASE 60 MG	49270020006530	Brand

Approval Criteria

1 - One of the following:

1.1 Trial and inadequate response to once daily PPI regimen

OR

1.2 A once daily PPI regimen is not appropriate to treat the patient's condition

AND

2 - Requested dose does not exceed maximum dose range found in labeling or supported by one of the following off label compendia for the requested product^:

American Hospital Formulary Service Drug Information

Micromedex Drug System

Clinical research in two articles from major peer reviewed medical journals that present data supporting requested dose as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes	Authorization of therapy will be issued for 12 months for all diagnoses, except for H. pylori eradication. For H. pylori eradication, authorization will be issued for 14 days. *These products may require step therapy. **Requests for greater than twice-daily dosing must be reviewed using the Quantity Limit General Administrative Guideline. ^Support found in labeling or compendia should be evaluated regardless of indication.

3 . Background

Clinical Practice Guidelines
BID Max Range Dosing Table [12-15] ***Intent of table below is to provide a quick reference for BID dosing range listed by requested product. If the requested dose exceeds max dose listed below, PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 9/4/24]**

	Aciphex (rabeprazole)	Dexilant (dexlansoprazole)	Nexium (esomeprazole)	Prevacid (Lansoprazole)	Prilosec (omeprazole)	Protonix (pantoprazole)	Zegerid (omeprazole/sodium bicarbonate)
DOSE RANGE	20 to 60 mg BID	30 mg BID	20 to 40 mg BID (Max = 240 mg/day)	30 to 90 mg BID	20 to 40mg BID (Max = 360 mg/day; divide doses above **80mg)**	40 to 80 mg BID (Max = 240 mg/day)	No BID support found at time of last annual review

4 . Endnotes

Both strengths of Zegerid capsule and powder for oral suspension have identical sodium bicarbonate content, respectively. Do not substitute two 20 mg capsules/packets for one 40 mg dose [4].

5 . References

Aciphex Prescribing Information. Eisai Inc. Woodcliff Lake, NJ. November 2020.

Aciphex Sprinkle Prescribing Information. Cerecor, Inc. Rockville, MD June 2018.

Esomeprazole Strontium Prescribing Information. Amneal Pharmaceuticals LLC. Glasgow, KY. January 2021.

Prilosec Prescribing Information. AstraZeneca Pharmaceuticals LP. wilmington, DE. March 2024.

Protonix Prescribing Information. Wyeth Pharmaceuticals, Inc. Philadelphia, PA. June 2023.

Zegerid Prescribing Information. Salix Pharmaceuticals. Bridgewater, NJ. July 2023.

Dexilant Prescribing Information. Takeda Pharmaceuticals America, Inc. Deerfield, IL. July 2023.

Nexium Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. July 2023.

Prevacid Prescribing Information. Takeda Pharmaceuticals, Inc. Deerfield, IL. August 2023.

First-Omeprazole Prescribing Information. Azurity Pharmaceuticals. Wilmington, MA. July 2020.

First-Lansoprazole Prescribing Information. Azurity Pharmaceuticals. Wilmington, MA. August 2020.

Micromedex solutions Web site. http://www.micromedexsolutions.com/home/dispatch. Accessed August 19, 2020.

Frazzoni M, Manno M, De Micheli E, Savarino V. Intra-oesophageal acid suppression in complicated gastro-oesophageal reflux disease: esomeprazole versus lansoprazole. Dig Liver Dis. 2006;38(2):85-90.

Huaiyuan G, Ma H, Wang J. Proton pump inhibitor therapy for the treatment of laryngopharyngeal reflux: a meta-analysis of randomized controlled trials. J Clin Gastroenterol. 2016;50(4):295-300.

Rees JRE, Lao-Sirieix P, Wong A, Fitzgerald RC. Treatment for Barrett's oesophagus. Cochrane Database of Syst Rev. 2010;1. Art. No.: CD004060. doi:10.1002/14651858.CD004060.pub2.

Konvomep Prescribing Information. Azurity Pharmaceuticals, Inc. Woburn, MA. August 2023.

6 . Revision History

Date	Notes
1/16/2025	Update program

Prior Authorization Guideline

Guideline ID	GL-229130
Guideline Name	Provigil (modafinil), Nuvigil (armodafinil)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Provigil (modafinil)
Narcolepsy Indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy. [1] **Obstructive sleep apnea (OSA)** Indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA). Limitations of Use: Provigil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating and during treatment with Provigil for excessive sleepiness. [1] **Shift work disorder (SWD)** Indicated to improve wakefulness in adult patients with excessive sleepiness associated with shift work disorder. [1] **Off Label Uses: Fatigue due to multiple sclerosis (MS)** In a double-blind, placebo-controlled study, treatment with modafinil significantly improved fatigue symptoms compared

with placebo in patients with multiple sclerosis (MS) [2,3]

Adjunctive therapy for the treatment of major depressive disorder (MDD) or bipolar disorder In a meta-analysis of 4 MDD RCTs and 2 bipolar depression RCTs, adjunctive treatment with modafinil improved overall depression scores, remission rates, and fatigue symptoms. [2,4]

Drug Name: Nuvigil (armodafinil)

Narcolepsy Indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy. [5]

Obstructive sleep apnea (OSA) Indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA). Limitations of Use: Nuvigil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating Nuvigil for excessive sleepiness. [5]

Shift work disorder (SWD) Indicated to improve wakefulness in adult patients with excessive sleepiness associated with shift work disorder. [5]

2 . Criteria

Product Name:Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 Months [A,1,5]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUVIGIL	ARMODAFINIL TAB 50 MG	61400010000310	Brand
NUVIGIL	ARMODAFINIL TAB 150 MG	61400010000330	Brand
NUVIGIL	ARMODAFINIL TAB 250 MG	61400010000340	Brand
MODAFINIL	MODAFINIL TAB 100 MG	61400024000310	Generic
MODAFINIL	MODAFINIL TAB 200 MG	61400024000320	Generic
PROVIGIL	MODAFINIL TAB 100 MG	61400024000310	Brand

PROVIGIL	MODAFINIL TAB 200 MG	61400024000320	Brand
NUVIGIL	ARMODAFINIL TAB 200 MG	61400010000335	
ARMODAFINIL	ARMODAFINIL TAB 50 MG	61400010000310	Generic
ARMODAFINIL	ARMODAFINIL TAB 150 MG	61400010000330	Generic
ARMODAFINIL	ARMODAFINIL TAB 200 MG	61400010000335	Generic
ARMODAFINIL	ARMODAFINIL TAB 250 MG	61400010000340	Generic

Approval Criteria

1 - Diagnosis of obstructive sleep apnea defined by one of the following: [6]

1.1 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [6,7,B,C]

OR

1.2 Both of the following: [6,7,B,C]

1.2.1 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

1.2.2 One of the following symptoms:

Unintentional sleep episodes during wakefulness

Daytime sleepiness

Unrefreshing sleep

Fatigue

Insomnia

Waking up breath holding, gasping, or choking

Loud snoring

Breathing interruptions during sleep

AND

2 - Both of the following:

2.1 Standard treatments for the underlying obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BPAP], etc.) have been used for 3 months or longer [2]

AND

2.2 Patient is fully compliant with standard treatment(s) for the underlying obstruction.

AND

3 - Trial and failure or intolerance to modafinil (applies to Provigil only)

AND

4 - Trial and failure or intolerance to armodafinil (applies to Nuvigil only)

Product Name:Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 Months [A,1,5]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUVIGIL	ARMODAFINIL TAB 50 MG	61400010000310	Brand
NUVIGIL	ARMODAFINIL TAB 150 MG	61400010000330	Brand
NUVIGIL	ARMODAFINIL TAB 250 MG	61400010000340	Brand

MODAFINIL	MODAFINIL TAB 100 MG	61400024000310	Generic
MODAFINIL	MODAFINIL TAB 200 MG	61400024000320	Generic
PROVIGIL	MODAFINIL TAB 100 MG	61400024000310	Brand
PROVIGIL	MODAFINIL TAB 200 MG	61400024000320	Brand
NUVIGIL	ARMODAFINIL TAB 200 MG	61400010000335	
ARMODAFINIL	ARMODAFINIL TAB 50 MG	61400010000310	Generic
ARMODAFINIL	ARMODAFINIL TAB 150 MG	61400010000330	Generic
ARMODAFINIL	ARMODAFINIL TAB 200 MG	61400010000335	Generic
ARMODAFINIL	ARMODAFINIL TAB 250 MG	61400010000340	Generic

Approval Criteria

1 - Patient continues to be fully compliant on concurrent standard treatment(s) for the underlying obstruction (e.g., CPAP, BPAP, etc.)

AND

2 - Patient is experiencing relief of symptomatic hypersomnolence with use

Product Name:Generic modafinil, Brand Provigil	
Diagnosis	Fatigue due to MS (off-label) [2,3,8,D]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROVIGIL	MODAFINIL TAB 100 MG	61400024000310	Brand
MODAFINIL	MODAFINIL TAB 100 MG	61400024000310	Generic
PROVIGIL	MODAFINIL TAB 200 MG	61400024000320	Brand
Modafinil	MODAFINIL TAB 200 MG	61400024000320	Generic

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient is experiencing fatigue

AND

3 - Used in combination with standard educational therapies (e.g., psychoeducation, behavioral programs, scheduled naps, additional non-pharmacological therapies, etc.)

AND

4 - Trial and failure or intolerance to modafinil (applies to Provigil only)

Product Name:Generic modafinil, Brand Provigil	
Diagnosis	Fatigue due to MS (off-label) [2,3,8,D]
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROVIGIL	MODAFINIL TAB 200 MG	61400024000320	Brand
modafinil	MODAFINIL TAB 200 MG	61400024000320	Generic
PROVIGIL	MODAFINIL TAB 100 MG	61400024000310	Brand
modafinil	MODAFINIL TAB 100 MG	61400024000310	Generic

Approval Criteria

1 - Patient is experiencing relief of fatigue with therapy

AND

2 - Used in combination with standard educational therapies (e.g., psychoeducation, behavioral programs, scheduled naps, additional non-pharmacological therapies, etc.)

Product Name:Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MODAFINIL	MODAFINIL TAB 100 MG	61400024000310	Generic
Provigil	MODAFINIL TAB 200 MG	61400024000320	Brand
Provigil	MODAFINIL TAB 100 MG	61400024000310	Brand
MODAFINIL	MODAFINIL TAB 200 MG	61400024000320	Generic
Nuvigil	ARMODAFINIL TAB 50 MG	61400010000310	Brand
Nuvigil	ARMODAFINIL TAB 150 MG	61400010000330	Brand
Nuvigil	ARMODAFINIL TAB 250 MG	61400010000340	Brand
NUVIGIL	ARMODAFINIL TAB 200 MG	61400010000335	
ARMODAFINIL	ARMODAFINIL TAB 50 MG	61400010000310	Generic
ARMODAFINIL	ARMODAFINIL TAB 150 MG	61400010000330	Generic
ARMODAFINIL	ARMODAFINIL TAB 200 MG	61400010000335	Generic
ARMODAFINIL	ARMODAFINIL TAB 250 MG	61400010000340	Generic

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [6,9-11,E-G]

AND

2 - Trial and failure or intolerance to modafinil (applies to Provigil only)

AND

3 - Trial and failure or intolerance to armodafinil (applies to Nuvigil only)

Product Name:Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MODAFINIL	MODAFINIL TAB 100 MG	61400024000310	Generic
Provigil	MODAFINIL TAB 200 MG	61400024000320	Brand
Provigil	MODAFINIL TAB 100 MG	61400024000310	Brand
MODAFINIL	MODAFINIL TAB 200 MG	61400024000320	Generic
Nuvigil	ARMODAFINIL TAB 50 MG	61400010000310	Brand
Nuvigil	ARMODAFINIL TAB 150 MG	61400010000330	Brand
Nuvigil	ARMODAFINIL TAB 250 MG	61400010000340	Brand
NUVIGIL	ARMODAFINIL TAB 200 MG	61400010000335	
ARMODAFINIL	ARMODAFINIL TAB 50 MG	61400010000310	Generic
ARMODAFINIL	ARMODAFINIL TAB 150 MG	61400010000330	Generic
ARMODAFINIL	ARMODAFINIL TAB 200 MG	61400010000335	Generic
ARMODAFINIL	ARMODAFINIL TAB 250 MG	61400010000340	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil

Diagnosis	Shift Work Disorder (SWD)
Approval Length	6 Months [A,1,5]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUVIGIL	ARMODAFINIL TAB 50 MG	61400010000310	Brand
NUVIGIL	ARMODAFINIL TAB 150 MG	61400010000330	Brand
NUVIGIL	ARMODAFINIL TAB 250 MG	61400010000340	Brand
MODAFINIL	MODAFINIL TAB 100 MG	61400024000310	Generic
MODAFINIL	MODAFINIL TAB 200 MG	61400024000320	Generic
PROVIGIL	MODAFINIL TAB 100 MG	61400024000310	Brand
PROVIGIL	MODAFINIL TAB 200 MG	61400024000320	Brand
NUVIGIL	ARMODAFINIL TAB 200 MG	61400010000335	
ARMODAFINIL	ARMODAFINIL TAB 50 MG	61400010000310	Generic
ARMODAFINIL	ARMODAFINIL TAB 150 MG	61400010000330	Generic
ARMODAFINIL	ARMODAFINIL TAB 200 MG	61400010000335	Generic
ARMODAFINIL	ARMODAFINIL TAB 250 MG	61400010000340	Generic

Approval Criteria

1 - Diagnosis of Shift Work Disorder confirmed by one of the following: [6,12]

1.1 Symptoms of excessive sleepiness or insomnia, for at least 3 months, which is temporally associated with a work period (usually night work) that occurs during the habitual sleep phase

OR

1.2 Sleep study demonstrating loss of a normal sleep wake pattern (i.e., disturbed chronobiologic rhythmicity)

AND

2 - Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia [6,12]

AND

3 - Trial and failure or intolerance to modafinil (applies to Provigil only)

AND

4 - Trial and failure or intolerance to armodafinil (applies to Nuvigil only)

Product Name:Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Shift Work Disorder (SWD)
Approval Length	6 Months [A,1,5]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUVIGIL	ARMODAFINIL TAB 50 MG	61400010000310	Brand
NUVIGIL	ARMODAFINIL TAB 150 MG	61400010000330	Brand
NUVIGIL	ARMODAFINIL TAB 250 MG	61400010000340	Brand
PROVIGIL	MODAFINIL TAB 100 MG	61400024000310	Brand
MODAFINIL	MODAFINIL TAB 200 MG	61400024000310	Generic
PROVIGIL	MODAFINIL TAB 100 MG	61400024000320	Brand
MODAFINIL	MODAFINIL TAB 200 MG	61400024000320	Generic
NUVIGIL	ARMODAFINIL TAB 200 MG	61400010000335	
ARMODAFINIL	ARMODAFINIL TAB 50 MG	61400010000310	Generic
ARMODAFINIL	ARMODAFINIL TAB 150 MG	61400010000330	Generic
ARMODAFINIL	ARMODAFINIL TAB 200 MG	61400010000335	Generic
ARMODAFINIL	ARMODAFINIL TAB 250 MG	61400010000340	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Generic modafinil, Brand Provigil	
Diagnosis	Adjunctive therapy for the treatment of major depressive disorder or bipolar depression (off-label) [2,4]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MODAFINIL	MODAFINIL TAB 100 MG	61400024000310	Generic
Provigil	MODAFINIL TAB 200 MG	61400024000320	Brand
Provigil	MODAFINIL TAB 100 MG	61400024000310	Brand
MODAFINIL	MODAFINIL TAB 200 MG	61400024000320	Generic

Approval Criteria

1 - Treatment-resistant depression, defined as both of the following:

1.1 Diagnosis of one of the following [4]:

Major depressive disorder (MDD)

Bipolar depression

AND

1.2 History of failure, contraindication, or intolerance to at least two antidepressants from different classes (e.g., SSRIs, SNRIs, bupropion)

AND

2 - Used as adjunctive therapy

AND

3 - Trial and failure or intolerance to modafinil (applies to Provigil only)

Product Name:Generic modafinil, Brand Provigil	
Diagnosis	Adjunctive therapy for the treatment of major depressive disorder or bipolar depression (off-label) [2,4]
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Provigil	MODAFINIL TAB 200 MG	61400024000320	Brand
Provigil	MODAFINIL TAB 100 MG	61400024000310	Brand
MODAFINIL	MODAFINIL TAB 200 MG	61400024000320	Generic
MODAFINIL	MODAFINIL 100MG	614002400310	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Used as adjunctive therapy

Product Name:Generic armodafinil 50 mg, Generic modafinil 100 mg, Brand Nuvigil 50 mg, or Brand Provigil 100 mg	
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
MODAFINIL	MODAFINIL TAB 100 MG	61400024000310	Generic

Provigil	MODAFINIL TAB 100 MG	61400024000310	Brand
Nuvigil	ARMODAFINIL TAB 50 MG	61400010000310	Brand
ARMODAFINIL	ARMODAFINIL TAB 50 MG	61400010000310	Generic

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication.

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements.

AND

2 - One of the following:

2.1 For titration purposes (one time authorization)

OR

2.2 Requested strength/dose is commercially unavailable

OR

2.3 Patient is on a dose alternating schedule

Notes	Authorization will be issued for the length of therapy based on indicati on, except for titration purposes (Narcolepsy: 12 months, All other indi cations: 6 months). Not to exceed maximum FDA-approved dose.

Product Name:Generic modafinil 200 mg, Brand Provigil 200 mg	
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
Provigil	MODAFINIL TAB 200 MG	61400024000320	Brand
MODAFINIL	MODAFINIL TAB 200 MG	61400024000320	Generic

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication.

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements.

AND

2 - History of inadequate response to Provigil 200 mg/day

AND

3 - One of the following:**

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of following compendia:

American Hospital Formulary Service Drug Information

Micromedex DRUGDEX System

Notes	Authorization will be issued for the length of therapy based on indicati on (Narcolepsy: 12 months, All other indications: 6 months). **NOTE: Published biomedical literature may be used as evidence to support s afety and additional efficacy at higher than maximum doses for the dia gnosis provided.

Product Name:Generic armodafinil 150 mg, Brand Nuvigil 150 mg, Generic armodafinil 200 mg, Brand Nuvigil 200 mg, Generic armodafinil 250 mg, or Brand Nuvigil 250 mg	
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
Nuvigil	Armodafinil 150 mg	61400010000330	Brand
Nuvigil	Armodafinil 250 mg	61400010000340	Brand
Nuvigil	Armodafinil 200 mg	61400010000335	Brand
ARMODAFINIL	ARMODAFINIL TAB 150 MG	61400010000330	Generic
ARMODAFINIL	ARMODAFINIL TAB 200 MG	61400010000335	Generic
ARMODAFINIL	ARMODAFINIL TAB 250 MG	61400010000340	Generic

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication.

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements.

AND

2 - One of the following**

2.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

2.2 Higher dose or quantity is supported by one of following compendia

American Hospital Formulary Service Drug Information

Micromedex DRUGDEX System

Notes	Authorization will be issued for the length of therapy based on indication, except for titration purposes (Narcolepsy: 12 months, All other indications: 6 months). Not to exceed maximum FDA-approved dose. NOTE: Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

Product Name:Brand Provigil 200mg, Generic modafinil 200mg	
Diagnosis	Narcolepsy: Twice-daily (BID) Therapy**
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
PROVIGIL	MODAFINIL TAB 200 MG	61400024000320	Brand
MODAFINIL	MODAFINIL TAB 200 MG	61400024000320	Generic

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [3,6,9-11,E-G]

AND

2 - One of the following

2.1 Trial and inadequate response to once daily treatment

OR **2.2** A once daily treatment is not appropriate to treat the patient's condition **AND** **3** - Requested dose does not exceed maximum dose range found in labeling or supported by one of the following off label compendia for the requested product: American Hospital Formulary Service Drug Information Micromedex Drug System Clinical research in two articles from major peer reviewed medical journals that present data supporting requested dose as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal	
Notes	**Requests for greater than twice-daily dosing must be reviewed using the Quantity Limit General Administrative Guideline.

3 . Definitions

Definition	Description
Cataplexy [13]	A sudden loss of muscle tone that leads to feelings of weakness and a loss of voluntary muscle control.
CPAP (continuous positive airway pressure) [13]	Delivers pressurized air from a machine into airways through a specially designed mask that is worn during sleep.
Multiple sleep latency test (MSLT) [13]	Assesses the severity of sleepiness by measuring the speed of falling asleep during a series of nap trials.
Narcolepsy [13]	A neurological condition in which people experience excessive daytime sleepiness, cataplexy, sleep paralysis, hallucinations and intermittent, uncontrollable sleep attacks during the daytime.

Non-Rapid Eye Movement (NREM) sleep [13]	One of the two basic states of sleep; consists of Stages 1, 2 (light sleep) and 3,4 (deep sleep).
Obstructive sleep apnea (OSA) [13]	The most common kind of sleep apnea. It is caused by a blockage of the upper airway.
Polysomnography (PSG) [13]	A test that records sleep architecture (i.e. the amount of NREM and REM sleep, number of arousals) and a variety of body functions during sleep, including breathing patterns, heart rhythms and limb movements. It is most commonly done to evaluate for sleep apnea.
Rapid Eye Movement (REM) sleep [13]	One of the two basic states of sleep. REM sleep, also known as "dream sleep," is characterized by rapid eye movements, and more irregular breathing and heart rate compared to NREM sleep.

4 . Endnotes

The effectiveness of modafinil (greater than 12 weeks for obstructive sleep apnea or SWD) and the effectiveness of armodafinil in long-term use (greater than 12 weeks) have not been systematically evaluated in placebo-controlled trials. [1,5]

International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for obstructive sleep apnea-hypopnea syndrome (OSAHS) include: One of the following: 1. Polysomnography (PSG) shows greater than or equal to 5 obstructive respiratory events per hour of sleep in a patient with one or more of the following: a. sleepiness, nonrestorative sleep, fatigue or insomnia symptoms b. waking up with breath holding, gasping or choking c. habitual snoring, breathing interruptions, or both noted by a bed partner or other observer d. hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation, or type 2 diabetes mellitus 2. Greater than or equal to 15 obstructive respiratory events per hour of sleep, regardless of the presence of associated symptoms or comorbidities. In addition, the disorder is not explained by another current sleep disorder, medical or neurological disorder, medication use, or substance use disorder [6].

Examples of obstructive respiratory events include: obstructive and mixed apneas, hypopneas, or respiratory effort related arousals (RERA) [6].

Despite lack of consistent clinical evidence or statement/guideline from a United States professional society, use of modafinil for fatigue is considered the standard practice in MS patients [8]. The 2022 National Institute for Health and Care Excellence guidance on MS lists modafinil as an option for managing fatigue in adults with MS [3].

The American Academy of Sleep Medicine (AASM) guidelines list modafinil as a "standard" patient care strategy (generally accepted patient-care strategy that reflects a high

degree of clinical certainty). [10] The use of modafinil for the treatment of narcolepsy is a strong recommendation. [9]

ICSD-3 diagnostic criteria for narcolepsy with cataplexy (narcolepsy type 1) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. One or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT); or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than 110 pg/mL or one-third of the normative values with the same standardized assay). 3. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [6,11]

ICSD-3 diagnostic criteria for narcolepsy without cataplexy (narcolepsy type 2) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. Cataplexy is absent 3. CSF hypocretin-1 levels, if measured, must not meet the narcolepsy type 1 criterion. 4. A mean sleep latency of less than or equal to 8 minutes and 2 or more SOREMPs on a MSLT performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT). 5. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [6,11]

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6 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228936
Guideline Name	Pulmonary Arterial Hypertension Agents
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Adcirca (tadalafil) Tablets, Alyq (tadalafil) Tablets, Tadliq (tadalafil) Oral Suspension
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with New York Heart Association (NYHA) Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).
Drug Name: Adempas (riociguat) Tablets
Pulmonary Arterial Hypertension (PAH) Indicated for treatment of adults with PAH (WHO Group I) to improve exercise capacity, WHO Functional Class, and to delay clinical worsening. Efficacy was shown in patients on riociguat monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominantly patients with WHO Functional Class II to III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%). **Chronic-Thromboembolic Pulmonary Hypertension (CTEPH)** Indicated for treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH),

(WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO Functional Class.

Drug Name: Flolan (epoprostenol sodium) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly (97%) patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (49%) or PAH associated with connective tissue diseases (51%).

Drug Name: Letairis (ambrisentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to 1) improve exercise ability and delay clinical worsening and 2) in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (60%) or PAH associated with connective tissue diseases (34%).

Drug Name: Liqrev (sildenafil) suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

Drug Name: Opsumit (macitentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to reduce the risks of disease progression and hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

Drug Name: Orenitram (treprostinil) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to delay disease progression and to improve exercise capacity. The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).

Drug Name: Opsynvi (macitentan/ tadalafil) Tablets

Pulmonary Arterial Hypertension Indicated for the chronic treatment of adults with pulmonary arterial hypertension (PAH, WHO Group I and WHO Functional Class (FC) II–III). Macitentan reduces the risk of clinical worsening events and hospitalization. Tadalafil improves exercise ability.

Drug Name: Remodulin (treprostinil sodium) Injection
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%). Indicated to diminish the rate of clinical deterioration in patients with PAH requiring transition from epoprostenol. Consider the risks and benefits of each drug prior to transition.
Drug Name: Revatio (sildenafil) Injection, Tablets, Oral Suspension
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I): 1) In adults to improve exercise ability and delay clinical worsening. 2) in pediatric patients 1 to 17 years old to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underlie improvements in exercise.
Drug Name: Tracleer (bosentan) Tablets, Tablets for Suspension
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I): 1) In adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to right shunts (18%). 2) In pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.
Drug Name: Tyvaso (treprostinil) Inhalation Solution, Tyvaso (treprostinil) DPI Inhalation Powder
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities. While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration. **Pulmonary Hypertension Associated with Interstitial Lung Disease (ILD)** Indicated for the treatment of pulmonary hypertension associated with ILD (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

Drug Name: Veletri (epoprostenol) Injection
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.
Drug Name: Ventavis (iloprost) Inhalation Solution
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration. Studies establishing effectiveness included predominately patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (65%) or PAH associated with connective tissue diseases (23%).
Drug Name: Uptravi (selexipag) Tablets and Injection
Pulmonary Arterial Hypertension Indicated for the treatment of PAH (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with WHO Functional Class II-III symptoms. Patients had idiopathic and heritable PAH (58%), PAH associated with connective tissue disease (29%), PAH associated with congenital heart disease with repaired shunts (10%).
Drug Name: Winrevair (sotatercept-csrk) Injection
Pulmonary Arterial Hypertension Indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group I) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.

2 . Criteria

Product Name:Generic Alyq tablet, Generic tadalafil tablet, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Generic ambrisentan tablet, Opsumit tablet, Orenitram tablet, Generic treprostinil injection, Generic sildenafil tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FLOLAN	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Brand
EPOPROSTENOL SODIUM	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Generic
FLOLAN	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Brand
EPOPROSTENOL SODIUM	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Generic
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
VENTAVIS	ILOPROST INHALATION SOLUTION 10 MCG/ML	40170060002020	Brand
VENTAVIS	ILOPROST INHALATION SOLUTION 20 MCG/ML	40170060002040	Brand
VELETRI	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Brand
VELETRI	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Brand
SILDENAFIL CITRATE	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Generic
TYVASO STARTER	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO REFILL	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
OPSUMIT	MACITENTAN TAB 10 MG	40160050000320	Brand
ADEMPAS	RIOCIGUAT TAB 0.5 MG	40134050000310	Brand
ADEMPAS	RIOCIGUAT TAB 1 MG	40134050000320	Brand
ADEMPAS	RIOCIGUAT TAB 1.5 MG	40134050000330	Brand
ADEMPAS	RIOCIGUAT TAB 2 MG	40134050000340	Brand
ADEMPAS	RIOCIGUAT TAB 2.5 MG	40134050000350	Brand
SILDENAFIL	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Generic
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 0.125 MG (BASE EQUIV)	40170080050410	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 0.25 MG (BASE EQUIV)	40170080050415	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 1 MG (BASE EQUIV)	40170080050420	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 2.5 MG (BASE EQUIV)	40170080050425	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 5 MG (BASE EQUIV)	40170080050435	Brand
TRACLEER	BOSENTAN TAB FOR ORAL SUSP 32 MG	40160015007320	Brand
TADALAFIL	TADALAFIL TAB 20 MG (PAH)	40143080000320	Generic
ALYQ	TADALAFIL TAB 20 MG (PAH)	40143080000320	Generic

AMBRISENTAN	AMBRISENTAN TAB 5 MG	40160007000310	Generic
AMBRISENTAN	AMBRISENTAN TAB 10 MG	40160007000320	Generic
TYVASO REFILL	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO STARTER	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
BOSENTAN	BOSENTAN TAB 62.5 MG	40160015000320	Generic
BOSENTAN	BOSENTAN TAB 125 MG	40160015000330	Generic
TREPROSTINIL	TREPROSTINIL INJ SOLN 20 MG/20ML (1 MG/ML)	40170080002050	Generic
TREPROSTINIL	TREPROSTINIL INJ SOLN 50 MG/20ML (2.5 MG/ML)	40170080002060	Generic
TREPROSTINIL	TREPROSTINIL INJ SOLN 100 MG/20ML (5 MG/ML)	40170080002070	Generic
TREPROSTINIL	TREPROSTINIL INJ SOLN 200 MG/20ML (10 MG/ML)	40170080002080	Generic
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 16 MCG/CARTRIDGE	40170080002920	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 32 MCG/CARTRIDGE	40170080002930	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 48 MCG/CARTRIDGE	40170080002940	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 64 MCG/CARTRIDGE	40170080002950	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 112 X 32MCG & 112 X 48MCG	40170080002960	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWDER 112 X 16MCG & 84 X 32MCG	40170080002970	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWD 112 X 16MCG & 112 X 32MCG & 28 X 48MCG	40170080002980	Brand
ORENITRAM TITRATION KIT MONTH 1	TREPROSTINIL TAB ER TITR PK (MO1) 126 X0.125MG & 42 X0.25MG	4017008005C110	Brand
ORENITRAM TITRATION KIT MONTH 2	TREPROSTINIL TAB ER TITR PK (MO2) 126 X0.125MG & 210 X0.25MG	4017008005C120	Brand
ORENITRAM TITRATION KIT MONTH 3	TREPROSTINIL TAB ER TITR PK(MO3)126X0.125MG&42X0.25MG&84X1MG	4017008005C130	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

Product Name:Brand Adcirca tablet, Tadliq oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADCIRCA	TADALAFIL TAB 20 MG (PAH)	40143080000320	Brand
TADLIQ	TADALAFIL ORAL SUSP 20 MG/5ML (PAH)	40143080001820	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

AND

5 - Trial and failure or intolerance to generic tadalfil

Product Name:Brand Letairis tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LETAIRIS	AMBRISENTAN TAB 5 MG	40160007000310	Brand
LETAIRIS	AMBRISENTAN TAB 10 MG	40160007000320	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

AND

5 - Trial and failure or intolerance to generic ambrisentan

Product Name:Opsynvi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OPSYNVI	MACITENTAN-TADALAFIL TAB 10-20 MG	40995502500310	Brand
OPSYNVI	MACITENTAN-TADALAFIL TAB 10-40 MG	40995502500320	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

1.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

2 - One of the following:

2.1 Trial and failure, contraindication or intolerance to generic ambrisentan

OR

2.2 Patient is currently being treated with a macitentan-containing product

AND

2 - Patient is unable to take Opsumit and generic tadalafil separately due to intolerance with Opsumit (e.g., allergy to excipient)

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

Product Name:Brand Remodulin injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REMODULIN	TREPROSTINIL INJ SOLN 20 MG/20ML (1 MG/ML)	40170080002050	Brand
REMODULIN	TREPROSTINIL INJ SOLN 50 MG/20ML (2.5 MG/ML)	40170080002060	Brand
REMODULIN	TREPROSTINIL INJ SOLN 100 MG/20ML (5 MG/ML)	40170080002070	Brand
REMODULIN	TREPROSTINIL INJ SOLN 200 MG/20ML (10 MG/ML)	40170080002080	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

AND

5 - Trial and failure or intolerance to generic treprostinil

Product Name:Brand Revatio tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVATIO	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

AND

5 - Trial and failure or intolerance to generic sildenafil tablet

Product Name:Brand Tracleer tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRACLEER	BOSENTAN TAB 62.5 MG	40160015000320	Brand
TRACLEER	BOSENTAN TAB 125 MG	40160015000330	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

AND

5 - Trial and failure or intolerance to generic bosentan tablet

Product Name:Brand Revatio injection or Generic sildenafil injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVATIO	SILDENAFIL CITRATE IV SOLN 10 MG/12.5ML (BASE EQUIVALENT)	40143060102020	Brand
SILDENAFIL	SILDENAFIL CITRATE IV SOLN 10 MG/12.5ML (BASE EQUIVALENT)	40143060102020	Generic

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

AND

5 - Patient is unable to take oral medications [2]

AND

6 - For Brand Revatio injection, trial and failure or intolerance to generic sildenafil injection

Product Name:Liqrev, Brand Revatio oral suspension or Generic sildenafil oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVATIO	SILDENAFIL CITRATE FOR SUSPENSION 10 MG/ML	40143060101920	Brand
SILDENAFIL CITRATE	SILDENAFIL CITRATE FOR SUSPENSION 10 MG/ML	40143060101920	Generic
LIQREV	SILDENAFIL CITRATE ORAL SUSP 10 MG/ML	40143060101825	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

AND

5 - For Brand Revatio oral suspension, trial and failure, or intolerance to both of the following:

Generic sildenafil tablets

Generic sildenafil oral suspension

AND

6 - For Liqrev, trial and failure or intolerance to generic sildenafil suspension

Product Name:Adempas tablet	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADEMPAS	RIOCIGUAT TAB 0.5 MG	40134050000310	Brand
ADEMPAS	RIOCIGUAT TAB 1 MG	40134050000320	Brand
ADEMPAS	RIOCIGUAT TAB 1.5 MG	40134050000330	Brand
ADEMPAS	RIOCIGUAT TAB 2 MG	40134050000340	Brand
ADEMPAS	RIOCIGUAT TAB 2.5 MG	40134050000350	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

AND

1.1.2 CTEPH is symptomatic

OR

1.2 Patient is currently on any therapy for the diagnosis of CTEPH

AND

2 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

Product Name:Tyvaso inhalation solution, Tyvaso Refill inhalation solution, or Tyvaso Start inhalation solution, Tyvaso DPI	
Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO STARTER	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO REFILL	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO REFILL	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO STARTER	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 16 MCG/CARTRIDGE	40170080002920	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 32 MCG/CARTRIDGE	40170080002930	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 48 MCG/CARTRIDGE	40170080002940	Brand

TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 64 MCG/CARTRIDGE	40170080002950	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 112 X 32MCG & 112 X 48MCG	40170080002960	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWDER 112 X 16MCG & 84 X 32MCG	40170080002970	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWD 112 X 16MCG & 112 X 32MCG & 28 X 48MCG	40170080002980	Brand

Approval Criteria

1 - Diagnosis of pulmonary hypertension associated with interstitial lung disease

AND

2 - Diagnosis of pulmonary hypertension associated with interstitial lung disease was confirmed by diagnostic test(s) (e.g., right heart catheterization, doppler echocardiogram, computerized tomography imaging)

AND

3 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

Product Name:Brand Adcirca tablet, Generic tadalafil tablet, Generic Alyq tablet, Tadliq oral suspension, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Brand Letairis tablet, Liqrev, Generic ambrisentan tablet, Opsynvi tablet, Opsumit tablet, Orenitram tablet, Brand Remodulin injection, Generic treprostinil injection, Brand Revatio injection, Generic sildenafil injection, Brand Revatio tablet, Generic sildenafil tablet, Brand Revatio oral suspension, Generic sildenafil oral suspension, Brand Tracleer tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution	
Diagnosis	All indications listed above

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADCIRCA	TADALAFIL TAB 20 MG (PAH)	40143080000320	Brand
LETAIRIS	AMBRISENTAN TAB 5 MG	40160007000310	Brand
LETAIRIS	AMBRISENTAN TAB 10 MG	40160007000320	Brand
TRACLEER	BOSENTAN TAB 62.5 MG	40160015000320	Brand
TRACLEER	BOSENTAN TAB 125 MG	40160015000330	Brand
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
VENTAVIS	ILOPROST INHALATION SOLUTION 10 MCG/ML	40170060002020	Brand
VENTAVIS	ILOPROST INHALATION SOLUTION 20 MCG/ML	40170060002040	Brand
FLOLAN	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Brand
EPOPROSTENOL SODIUM	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Generic
FLOLAN	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Brand
EPOPROSTENOL SODIUM	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Generic
VELETRI	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Brand
VELETRI	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Brand
OPSUMIT	MACITENTAN TAB 10 MG	40160050000320	Brand
ADEMPAS	RIOCIGUAT TAB 0.5 MG	40134050000310	Brand
ADEMPAS	RIOCIGUAT TAB 1 MG	40134050000320	Brand
ADEMPAS	RIOCIGUAT TAB 1.5 MG	40134050000330	Brand
ADEMPAS	RIOCIGUAT TAB 2 MG	40134050000340	Brand
ADEMPAS	RIOCIGUAT TAB 2.5 MG	40134050000350	Brand
REVATIO	SILDENAFIL CITRATE IV SOLN 10 MG/12.5ML (BASE EQUIVALENT)	40143060102020	Brand
REVATIO	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Brand
SILDENAFIL CITRATE	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Generic
TYVASO STARTER	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO REFILL	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand

SILDENAFIL	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Generic
SILDENAFIL	SILDENAFIL CITRATE IV SOLN 10 MG/12.5ML (BASE EQUIVALENT)	40143060102020	Generic
TRACLEER	BOSENTAN TAB FOR ORAL SUSP 32 MG	40160015007320	Brand
TADALAFIL	TADALAFIL TAB 20 MG (PAH)	40143080000320	Generic
ALYQ	TADALAFIL TAB 20 MG (PAH)	40143080000320	Generic
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 0.125 MG (BASE EQUIV)	40170080050410	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 0.25 MG (BASE EQUIV)	40170080050415	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 1 MG (BASE EQUIV)	40170080050420	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 2.5 MG (BASE EQUIV)	40170080050425	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 5 MG (BASE EQUIV)	40170080050435	Brand
AMBRISENTAN	AMBRISENTAN TAB 10 MG	40160007000320	Generic
AMBRISENTAN	AMBRISENTAN TAB 5 MG	40160007000310	Generic
BOSENTAN	BOSENTAN TAB 62.5 MG	40160015000320	Generic
BOSENTAN	BOSENTAN TAB 125 MG	40160015000330	Generic
SILDENAFIL CITRATE	SILDENAFIL CITRATE FOR SUSPENSION 10 MG/ML	40143060101920	Generic
REMODULIN	TREPROSTINIL INJ SOLN 20 MG/20ML (1 MG/ML)	40170080002050	Brand
TREPROSTINIL	TREPROSTINIL INJ SOLN 20 MG/20ML (1 MG/ML)	40170080002050	Generic
REMODULIN	TREPROSTINIL INJ SOLN 50 MG/20ML (2.5 MG/ML)	40170080002060	Brand
TREPROSTINIL	TREPROSTINIL INJ SOLN 50 MG/20ML (2.5 MG/ML)	40170080002060	Generic
REMODULIN	TREPROSTINIL INJ SOLN 100 MG/20ML (5 MG/ML)	40170080002070	Brand
TREPROSTINIL	TREPROSTINIL INJ SOLN 100 MG/20ML (5 MG/ML)	40170080002070	Generic
REMODULIN	TREPROSTINIL INJ SOLN 200 MG/20ML (10 MG/ML)	40170080002080	Brand
TREPROSTINIL	TREPROSTINIL INJ SOLN 200 MG/20ML (10 MG/ML)	40170080002080	Generic
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 16 MCG/CARTRIDGE	4017008000292	Brand

TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 32 MCG/CARTRIDGE	40170080002930	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 48 MCG/CARTRIDGE	40170080002940	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 64 MCG/CARTRIDGE	40170080002950	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 112 X 32MCG & 112 X 48MCG	40170080002960	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWDER 112 X 16MCG & 84 X 32MCG	40170080002970	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWD 112 X 16MCG & 112 X 32MCG & 28 X 48MCG	40170080002980	Brand
TADLIQ	TADALAFIL ORAL SUSP 20 MG/5ML (PAH)	40143080001820	Brand
ORENITRAM TITRATION KIT MONTH 1	TREPROSTINIL TAB ER TITR PK (MO1) 126 X0.125MG & 42 X0.25MG	4017008005C110	Brand
ORENITRAM TITRATION KIT MONTH 2	TREPROSTINIL TAB ER TITR PK (MO2) 126 X0.125MG & 210 X0.25MG	4017008005C120	Brand
ORENITRAM TITRATION KIT MONTH 3	TREPROSTINIL TAB ER TITR PK(MO3)126X0.125MG&42X0.25MG&84X1MG	4017008005C130	Brand
LIQREV	SILDENAFIL CITRATE ORAL SUSP 10 MG/ML	40143060101825	Brand
REVATIO	SILDENAFIL CITRATE FOR SUSPENSION 10 MG/ML	40143060101920	Brand
OPSYNVI	MACITENTAN-TADALAFIL TAB 10-20 MG	40995502500310	Brand
OPSYNVI	MACITENTAN-TADALAFIL TAB 10-40 MG	40995502500320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - For Brand Revatio injection, Brand Tracleer, Brand Adcirca, Brand Letairis, Brand Remodulin injection, and Brand Revatio tablet, trial and failure or intolerance to its generic counterpart

AND

3 - For Brand Revatio oral suspension, trail and failure or intolerance to both of the following:

Generic sildenafil tablets

Generic sildenafil oral suspension

AND

4 - For Tadliq oral suspension, trial and failure or intolerance to generic tadalafil

AND

5 - For Liqrev, trial and failure or intolerance to generic sildenafil suspension

AND

6 - For Opsynvi, patient is unable to take Opsumit and generic tadalafil separately due to intolerance with Opsumit (e.g., allergy to excipient)

Product Name:Uptravi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UPTRAVI	SELEXIPAG TAB THERAPY PACK 200 MCG (140) & 800 MCG (60)	4012007000B720	Brand
UPTRAVI	SELEXIPAG TAB 200 MCG	40120070000310	Brand
UPTRAVI	SELEXIPAG TAB 400 MCG	40120070000315	Brand
UPTRAVI	SELEXIPAG TAB 600 MCG	40120070000320	Brand

UPTRAVI	SELEXIPAG TAB 800 MCG	40120070000325	Brand
UPTRAVI	SELEXIPAG TAB 1000 MCG	40120070000330	Brand
UPTRAVI	SELEXIPAG TAB 1200 MCG	40120070000335	Brand
UPTRAVI	SELEXIPAG TAB 1400 MCG	40120070000340	Brand
UPTRAVI	SELEXIPAG TAB 1600 MCG	40120070000345	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to one of the following:

PDE-5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)]

Adempas (riociguat)

AND

4.1.2 Trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

Product Name:Uptravi injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UPTRAVI	SELEXIPAG FOR IV SOLN 1800 MCG	40120070002120	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to one of the following:

PDE-5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)]

Adempas (riociguat)

AND

4.1.2 Trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

AND

6 - Patient is unable to take oral medications [13]

Product Name:Uptravi tablet/injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UPTRAVI	SELEXIPAG TAB THERAPY PACK 200 MCG (140) & 800 MCG (60)	4012007000B720	Brand
UPTRAVI	SELEXIPAG TAB 200 MCG	40120070000310	Brand
UPTRAVI	SELEXIPAG TAB 400 MCG	40120070000315	Brand
UPTRAVI	SELEXIPAG TAB 600 MCG	40120070000320	Brand
UPTRAVI	SELEXIPAG TAB 800 MCG	40120070000325	Brand
UPTRAVI	SELEXIPAG TAB 1000 MCG	40120070000330	Brand
UPTRAVI	SELEXIPAG TAB 1200 MCG	40120070000335	Brand
UPTRAVI	SELEXIPAG TAB 1400 MCG	40120070000340	Brand
UPTRAVI	SELEXIPAG TAB 1600 MCG	40120070000345	Brand
UPTRAVI	SELEXIPAG FOR IV SOLN 1800 MCG	40120070002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Winrevair Injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 45 MG	40110070206420	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 60 MG	40110070206425	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 2 X 45 MG	40110070206430	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 2 X 60 MG	40110070206435	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - Patient is currently on at least two therapies indicated for the treatment of pulmonary arterial hypertension from the following different mechanisms of action, unless there is a contraindication or intolerance:

Endothelin receptor antagonists (i.e., Bosentan, ambrisentan or macitentan)

Phosphodiesterase 5 inhibitors (i.e., Tadalafil or sildenafil)

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Cardiologist

Product Name:Winrevair Injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 45 MG	40110070206420	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 60 MG	40110070206425	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 2 X 45 MG	40110070206430	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 2 X 60 MG	40110070206435	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

Require right heart catheterization in order to confirm pulmonary arterial hypertension diagnosis: Per clinical consult with cardiologist, PAH specialist, and P&T committee recommendation, February 20, 2014.

4 . References

Flolan Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. October 2023.

Revatio Prescribing Information. Viatris Specialty LLC. Morgantown, WV. January 2023.

Ventavis Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. March 2022.

Tyvaso Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. May 2022.

Remodulin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. October 2023.

Adcirca Prescribing Information. Eli Lilly and Company. Indianapolis, IN. September 2020.

Letairis Prescribing Information. Gilead Sciences, Inc. Foster City, CA. August 2019.

Tracleer Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.

Veletri Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.

Opsumit Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. June 2023.

Adempas Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. September 2021.

Orenitram Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. August 2023.

Uptravi Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.

Alyq Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. September 2021.

Tyvaso DPI Prescribing Information. United Therapeutics Corporation. Research Triangle Park, NC. June 2023.

Tadliq Prescribing Information. CMP Pharma, Inc. Farmville, NC. October 2023.

Liqrev Prescribing Information. CMP Pharma, Inc. Farmville, NC. April 2023.

Winrevair Prescribing Information. Merck Sharp & Dohme LLC. March 2023

Opsynvi Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. April 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Pulmozyme (dornase alfa inhalation solution)

Prior Authorization Guideline

Guideline ID	GL-228942
Guideline Name	Pulmozyme (dornase alfa inhalation solution)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Pulmozyme (dornase alpha) Inhalation Solution
Cystic Fibrosis Indicated, in conjunction with standard therapies, for the management of pediatric and adult patients with cystic fibrosis (CF) to improve pulmonary function. In CF patients with an FVC ≥ 40% of predicted, daily administration of PULMOZYME has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

2 . Criteria

Product Name:Pulmozyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PULMOZYME	DORNASE ALFA INHAL SOLN 1 MG/ML	45304020002010	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF) [2,3]

Product Name:Pulmozyme	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PULMOZYME	DORNASE ALFA INHAL SOLN 1 MG/ML	45304020002010	Brand
PULMOZYME	DORNASE ALFA INHAL SOLN 2.5 MG/2.5ML	45304020002010	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient demonstrates positive clinical response (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations) to therapy

3 . References

Pulmozyme Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2024.

Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013;187(7):680-9.

Flume PA, O'Sullivan BP, Robinson KA et al. Cystic fibrosis pulmonary guidelines. Am J Respir Crit Care Med. 2007;176:957-969

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228710
Guideline Name	Pyrukynd (mitapivat)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Pyrukynd (mitapivat)
Hemolytic Anemia Indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

2 . Criteria

Product Name:Pyrukynd	
Diagnosis	Hemolytic Anemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PYRUKYND TAPER PACK	MITAPIVAT SULFATE TAB THERAPY PACK 5 MG	8587005070B710	Brand
PYRUKYND TAPER PACK	MITAPIVAT SULFATE TAB THERAPY PACK 7 X 20 MG & 7 X 5 MG	8587005070B720	Brand
PYRUKYND TAPER PACK	MITAPIVAT SULFATE TAB THERAPY PACK 7 X 50 MG & 7 X 20 MG	8587005070B735	Brand
PYRUKYND	MITAPIVAT SULFATE TAB 5 MG	85870050700310	Brand
PYRUKYND	MITAPIVAT SULFATE TAB 20 MG	85870050700325	Brand
PYRUKYND	MITAPIVAT SULFATE TAB 50 MG	85870050700340	Brand

Approval Criteria

1 - Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count) [A, 2, 3, 4]

AND

2 - Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene: [B, 1, 2, 4, 5]

Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant

Patients is not homozygous for the c.1436G>A (p.R479H) variant

Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

AND

3 - Hemoglobin is less than or equal to 10g/dL [1]

AND

4 - Patient has symptomatic anemia or is transfusion dependent [7]

AND

5 - Exclusion of other causes of hemolytic anemias (e. g., infections, toxins, drugs) [C, 2, 5]

AND

6 - Prescribed by or in consultation with a hematologist

Product Name:Pyrukynd	
Diagnosis	Hemolytic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PYRUKYND TAPER PACK	MITAPIVAT SULFATE TAB THERAPY PACK 5 MG	8587005070B710	Brand
PYRUKYND TAPER PACK	MITAPIVAT SULFATE TAB THERAPY PACK 7 X 20 MG & 7 X 5 MG	8587005070B720	Brand
PYRUKYND TAPER PACK	MITAPIVAT SULFATE TAB THERAPY PACK 7 X 50 MG & 7 X 20 MG	8587005070B735	Brand
PYRUKYND	MITAPIVAT SULFATE TAB 5 MG	85870050700310	Brand
PYRUKYND	MITAPIVAT SULFATE TAB 20 MG	85870050700325	Brand
PYRUKYND	MITAPIVAT SULFATE TAB 50 MG	85870050700340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy [e.g., hemoglobin increase greater than or equal to 1.5g/dL from baseline, reduction in transfusions of greater than or equal to 33% in the number of red blood cell units transfused during the fixed dose period compared with the patient's historical transfusion burden, improvement in markers of

hemolysis from baseline (e.g., bilirubin, lactated dehydrogenase [LDH], haptoglobin, reticulocyte count)] **AND** **2** - Prescribed by or in consultation with a hematologist	
Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a 1-month authorization should be issued one time for Pyrukynd gradual therapy discontinuation.

3 . Endnotes

The first step in the evaluation of a person with possible PK deficiency is to establish if hemolysis is present. Hemolytic anemia is characterized by an increased reticulocyte count, increased indirect bilirubin, and possibly by increased LDH and decreased haptoglobin [4]

In case of decreased PK activity, sequencing of PKLR gene is highly recommended to confirm the diagnosis [2]

Since the hematological features of PK deficiency are not specific, the possibility of PK deficiency and other metabolic abnormalities should be considered in all patients displaying chronic hemolysis where an immune-mediated hemolytic process, red cell membrane defect, unstable hemoglobin, or paroxysmal nocturnal hemoglobinuria has been excluded [2]

4 . References

Pyrukynd (mitapivat) [prescribing information]. Agios Pharmaceuticals, Inc. Cambridge, MA. February 2022.

Bianchi, P., Fermo, E. et al. Addressing the diagnostic gaps in pyruvate kinase deficiency: Consensus recommendations on the diagnosis of pyruvate kinase deficiency. Available at https://doi.org/10.1002/ajh.25325. October 25, 2018. Accessed March 28, 2022.

National Organization for Rare Disorders and Foundation for Rare Blood Diseases. Voice of the Patient Report Pyruvate Kinase Deficiency. Available at https://rarediseases.org/wp-content/uploads/2020/01/NRD-2029-Voice-of-the-Patient-Report-PKD_FNL-1.pdf. Accessed March 28,2022.

UpToDate Pyruvate Kinase Deficiency. Available at https://www.uptodate.com/contents/pyruvate-kinase-deficiency. Accessed April 1, 2024.

Samkari-Al, H., Van Beers, E. et al. The variable manifestations of disease in pyruvate kinase deficiency and their management. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7556504/. Accessed March 28, 2022.

Clinical consult April 8, 2022.

May P & T Committe feedback. May 19, 2022.

Samkari, H., Shehata, N., Robertson, K., et al. Diagnosis and management of pyruvate kinase deficiency: international expert guidelines. Available at : https://thalassaemia.org.cy/wp-content/uploads/2024/03/PKD-Guidelines-LancetHaem-02-2024-1.pdf. Accessed April 1, 2024.

Prior Authorization Guideline

Guideline ID	GL-228943
Guideline Name	Qinlock (ripretinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Qinlock (ripretinib)
Gastrointestinal Stromal Tumor (GIST) Indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

2 . Criteria

Product Name:Qinlock	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QINLOCK	RIPRETINIB TAB 50 MG	21533053000320	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Disease is advanced

AND

3 - Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib

Product Name:Qinlock	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QINLOCK	RIPRETINIB TAB 50 MG	21533053000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Qinlock Prescribing Information. Deciphera Pharmaceuticals, LLC. Waltham, MA. October 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228945
Guideline Name	Quantity Limit General
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Drugs subjected to Quantity Limits (in the absence of a drug-specific guideline)*	
Approval Length	6 Month(s) (except for titration or loading-dose purposes)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Quantity limit general			
Quantity			

Approval Criteria

1 - One of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - One of the following:

2.1 For titration or loading-dose purposes (one time authorization or per FDA labeling)

OR

2.2 Requested strength/dose is commercially unavailable**

OR

2.3 Patient is on a dose alternating schedule

OR

2.4 For topical applications, member has tried the dose under the quantity limit restriction for an adequate period of time and it has been deemed ineffective or insufficient in the treatment of the member's disease or medical condition

AND

3 - For the indication being requested, the higher dose, frequency of administration, and quantity are supported in one of the following:

3.1 The dosage and administration section of the manufacturer's prescribing information

OR **3.2** One of following compendia: American Hospital Formulary Service Drug Information Micromedex DRUGDEX System **OR** **3.3** Supported as being generally safe and effective by clinical research in two articles from peer reviewed medical journals	
Notes	*This guideline only applies in the absence of a drug-specific quantity l imit override guideline. No override requests will be permitted for acet aminophen, alone or in combination with other agents, which will exce ed a total of 4 grams of acetaminophen per day. **Commercially avail able strength/dose requires a formulary drug.

2 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233339
Guideline Name	Radicava (edaravone)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	3/1/2025
P&T Approval Date:	7/26/2017
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Radicava (edaravone) injection, Radicava ORS (edaravone) oral suspension
Amyotrophic Lateral Sclerosis (ALS) Indicated for the treatment of Amyotrophic Lateral Sclerosis (ALS).

2 . Criteria

Product Name:Brand Radicava IV, generic edaravone IV, Radicava ORS	
Diagnosis	Amyotrophic Lateral Sclerosis (ALS)
Approval Length	6 Months [A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RADICAVA	EDARAVONE INJ 30 MG/100ML (0.3 MG/ML)	74509030002010	Brand
RADICAVA ORS STARTER KIT	EDARAVONE ORAL SUSP 105 MG/5ML	74509030001820	Brand
RADICAVA ORS	EDARAVONE ORAL SUSP 105 MG/5ML	74509030001820	Brand
EDARAVONE	EDARAVONE INJ 30 MG/100ML (0.3 MG/ML)	74509030002010	Generic
EDARAVONE	EDARAVONE INJ 60 MG/100ML (0.6 MG/ML)	74509030002014	Generic

Approval Criteria

1 - Diagnosis of “definite” or “probable” amyotrophic lateral sclerosis (ALS) per the revised EL Escorial and Airlie House diagnostic criteria

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

AND

3 - Patient has scores greater than or equal to 2 in all items of the ALS Functional Rating Scale-Revised (ALSFRS-R) criteria at the start of treatment

AND

4 - Patient has a percent (%) forced vital capacity (%FVC) greater than or equal to 80% at the start of treatment

AND

5 - Patient is not dependent on invasive ventilation or tracheostomy

Product Name:Brand Radicava IV, generic edaravone IV, Radicava ORS	
Diagnosis	Amyotrophic Lateral Sclerosis (ALS)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RADICAVA	EDARAVONE INJ 30 MG/100ML (0.3 MG/ML)	74509030002010	Brand
RADICAVA ORS STARTER KIT	EDARAVONE ORAL SUSP 105 MG/5ML	74509030001820	Brand
RADICAVA ORS	EDARAVONE ORAL SUSP 105 MG/5ML	74509030001820	Brand
EDARAVONE	EDARAVONE INJ 30 MG/100ML (0.3 MG/ML)	74509030002010	Generic
EDARAVONE	EDARAVONE INJ 60 MG/100ML (0.6 MG/ML)	74509030002014	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.(e.g., slowing in the decline of functional abilities)

AND

2 - Patient is not dependent on invasive ventilation or tracheostomy

3 . Endnotes

Authorization period is based on the pivotal study duration of 24 weeks. [1-3]

4 . References

Abe K, Itoyama Y, Sobue G, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. Amyotroph Lateral Scler Frontotemporal Degener. 2014; 15(7-8):610-7.

Radicava Prescribing Information. Mitsubishi Tanabe Pharma. December 2022.

The Writing Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomized, double-blind, placebo-controlled trial. Lancet Neurol 2017; 16(7):505-512.

Radicava ORS Prescribing Information. Mitsubishi Tanabe Pharma. Jersey City, NJ. May 2022.

Edaravone Injection Prescribing Information. Piramal Crtical Care, Inc. Bethlehem, PA. May 2024.

5 . Revision History

Date	Notes
2/26/2025	Quartz Comm copied to mirrow Optum Rx

Prior Authorization Guideline

Guideline ID	GL-228947
Guideline Name	Reblozyl (luspatercept-aamt)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Reblozyl (luspatercept-aamt)
Beta Thalassemia Indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia. **Myelodysplastic Syndromes with Ring Sideroblasts or Myelodysplastic/ Myeloproliferative Neoplasm with Ring Sideroblasts and Thrombocytosis Associated Anemia** Indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia. **Myelodysplastic Syndromes Associated Anemia** Indicated for the treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red

blood cell (RBC) transfusions. Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

2 . Criteria

Product Name:Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 25 MG	82400540102120	Brand
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 75 MG	82400540102140	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of beta thalassemia major [3]

AND

1.1.2 Patient requires regular red blood cell (RBC) transfusions

OR

1.2 Diagnosis of transfusion-dependent beta thalassemia [3]

AND

2 - Prescribed by or in consultation with one of the following:

Hematologist

Oncologist

Product Name:Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 25 MG	82400540102120	Brand
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 75 MG	82400540102140	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in RBC transfusion burden) [1,2]

Product Name:Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 25 MG	82400540102120	Brand
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 75 MG	82400540102140	Brand

Approval Criteria

1 - One of the following diagnoses:

1.1 Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS)

OR

1.2 Myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

AND

2 - Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

4 - Prescribed by or in consultation with one of the following:

Hematologist

Oncologist

Product Name:Reblozyl	
Diagnosis	Myelodysplastic Syndromes

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 25 MG	82400540102120	Brand
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 75 MG	82400540102140	Brand

Approval Criteria

1 - Diagnosis of very low- to intermediate-risk myelodysplastic syndromes (MDS)

AND

2 - Patient does not have previous erythropoiesis stimulating agent use (ESA-naïve)

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

4 - Prescribed by or in consultation with one of the following:

Hematologist

Oncologist

Product Name:Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 25 MG	82400540102120	Brand
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 75 MG	82400540102140	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., RBC transfusion independence, improvement in hemoglobin levels) [1,4]

3 . References

Reblozyl Prescribing Information. Celgene Corporation. Summit, NJ. August 2023.

Piga A, Perrotta S, Gamberini M, et al. Luspatercept improves hemoglobin levels and blood transfusion requirements in a study of patients with β-thalassemia. Blood 2019; 133 (12): 1279–1289.

Per clinical consult with oncologist, December 19, 2019.

Fenaux P, Platzbecker U, Ghulam J, et al. Luspatercept in patients with lower-risk myelodysplastic syndromes. N Engl J Med 2020; 382:140-151.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228712
Guideline Name	Recorlev (levoketoconazole) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Recorlev (levoketoconazole)
Cushing's Syndrome Indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative. Limitations of Use: RECORLEV is not approved for the treatment of fungal infections. The safety and effectiveness of RECORLEV for the treatment of fungal infections have not been established

2 . Criteria

Product Name:Recorlev	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RECORLEV	LEVOKETOCONAZOLE TAB 150 MG	30022040000320	Brand

Approval Criteria

1 - Diagnosis of Cushing's syndrome demonstrated by urinary free cortisol (UFC) increase of 50% from baseline [3]

AND

2 - Patient is being treated for endogenous hypercortisolemia (e.g., pituitary adenoma, ectopic tumor, adrenal adenoma)[1,2]

AND

3 - One of the following:

3.1 Patient is not a candidate for surgery

OR

3.2 Surgery has not been curative

AND

4 - Trial and failure for a minimum of 90 days, or intolerance to oral ketoconazole [A]

AND

5 - Prescribed by or in consultation with an endocrinologist

Product Name:Recorlev	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RECORLEV	LEVOKETOCONAZOLE TAB 150 MG	30022040000320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as demonstrated by ONE of the following:

Normalization of urinary free cortisol (UFC) [1]

At least a 50% decrease in UFC levels [3]

AND

2 - Trial and failure for a minimum of 90 days, or intolerance to oral ketoconazole [A]

Product Name:Recorlev	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
RECORLEV	LEVOKETOCONAZOLE TAB 150 MG	30022040000320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Cushing's syndrome demonstrated by urinary free cortisol (UFC) increase of 50% from baseline [3]

AND

2 - Patient is being treated for endogenous hypercortisolemia (e.g., pituitary adenoma, ectopic tumor, adrenal adenoma)[1,2]

AND

3 - One of the following:

3.1 Patient is not a candidate for surgery

OR

3.2 Surgery has not been curative

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure for a minimum of 90 days, or intolerance to oral ketoconazole [A]

AND

5 - Prescribed by or in consultation with an endocrinologist

3 . Endnotes

Per feedback from consultant, determining efficacy of ketoconazole therapy is difficult to determine as multiple dose adjustments often need to be made depending on patient's response. Consultant recommends failure to respond to therapy be defined as requiring more than 3-4 dose adjustments or no response after 4 months. [3]

4 . References

Recorlev [prescribing information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; June 2023.

Guaraldi F, Salvatori R. Cushing Syndrome: Maybe Not So Uncommon of an Endocrine Disease. The Journal of the American Board of Family Medicine. 2012;25(2):199-208.

Per clinical consult with endocrinologist, February 11, 2022.

Regranex (becaplermin)

Prior Authorization Guideline

Guideline ID	GL-228949
Guideline Name	Regranex (becaplermin)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Regranex Gel (becaplermin)
Diabetic Neuropathic Ulcers Indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, when used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control. Limitations of Use: The efficacy of Regranex Gel has not been established for the treatment of pressure ulcers and venous stasis ulcers and has not been evaluated for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue (Stage I or II, IAET staging classification) or ischemic diabetic ulcers. The effects of becaplermin on exposed joints, tendons, ligaments, and bone have not been established in humans. Regranex is not intended to be used in wounds that close by primary intention.

2 . Criteria

Product Name:Regranex	
Approval Length	5 Months [1, A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REGRANEX	BECAPLERMIN GEL 0.01%	90945020004020	Brand

Approval Criteria

1 - Patient has a lower extremity diabetic neuropathic ulcer

AND

2 - Treatment will be given in combination with ulcer wound care (e.g., debridement, infection control, and/or pressure relief) [1]

3 . Endnotes

Fifty percent of patients will achieve complete healing within 20 weeks with Regranex. Reassessment is required for further therapy. [1] If the ulcer does not decrease in size by approximately 30% after 10 weeks of treatment or complete healing has not occurred in 20 weeks, continued treatment with Regranex should be reassessed. Postmarketing studies have demonstrated an increased risk of mortality secondary to malignancy observed in patients treated with greater than or equal to 3 tubes of Regranex gel. [1]

4 . References

Regranex Prescribing Information. Smith & Nephew, Inc. Fort Worth, TX. August 2019.

5 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228714
Guideline Name	Relyvrio (sodium phenylbutyrate and taurursodiol)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Relyvrio (sodium phenylbutyrate and taurursodiol)
Amyotrophic lateral sclerosis Indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults.

2 . Criteria

Product Name:Relyvrio	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - Diagnosis amyotrophic lateral sclerosis (ALS)

AND

2 - Diagnosis of ALS is further supported by neurogenic changes in electromyography (EMG) [2]

AND

3 - Patient has had ALS symptoms for less than or equal to 18 months

AND

4 - Patient has a percent (%) forced vital capacity (%FVC) or slow vital capacity (%SVC) greater than or equal to 60% at the start of treatment

AND

5 - Patient does not require permanent noninvasive ventilation or invasive ventilation

AND

6 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

Product Name:Relyvrio	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RELYVRIO	SODIUM PHENYLBUTYRATE-TAURURSODIOL POWD PACK 3-1 GM	74509902703020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., slowed disease progression)

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

3 . Endnotes

Great care should be taken to rule out diseases that can masquerade as ALS. An evolution of atypical symptoms and a lack of progression of typical symptoms are the most important "red flags" suggesting an alternative diagnosis. [2]

4 . References

Paganoni S, Macklin EA, Hendrix S, et al. Trial of Sodium Phenylbutyrate–Taurursodiol for Amyotrophic Lateral Sclerosis. New England Journal of Medicine. 2020;383(10):919-930.

Andersen PM, Abrahams S, Borasio GD, et al. EFNS guidelines on the Clinical Management of Amyotrophic Lateral Sclerosis (MALS) - revised report of an EFNS task force. European Journal of Neurology.

Paganoni S, Hendrix S, Dickson SP, et al. Long-term survival of participants in the CENTAUR trial of sodium phenylbutyrate-taurursodiol in amyotrophic lateral sclerosis. Muscle & Nerve. 2021;63(1):31-39.

ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/study/NCT03127514. Accessed May 26, 2022.

Galvez-Jimenez N, Goyal NA. Disease-modifying treatment of amyotrophic lateral sclerosis. UpToDate Web site. http://www.uptodate.com. Accessed May 26, 2022.

Elman LB, McCluskey, L. Diagnosis of amyotrophic lateral sclerosis and other forms of motor neuron disease. UpToDate Web site. http://www.uptodate.com. Accessed May 26, 2022.

Relyvrio Prescribing Information. Amylyx Pharmaceuticals, Inc. Cambridge, MA. September 2022.

Prior Authorization Guideline

Guideline ID	GL-228951
Guideline Name	Repository Corticotropin Gel Products - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Acthar Gel (repository corticotropin injection)
Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. **Exacerbations of Multiple Sclerosis [4, 5]** Indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease. **All Other Disease States [A]** *Please Note: The request for Acthar for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions. **[Non-Approvable Use] Rheumatic Disorders* [6, 7, A]** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-

dose maintenance therapy), Ankylosing spondylitis.

[Non-Approvable Use] Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

[Non-Approvable Use] Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome.

[Non-Approvable Use] Allergic States* [A] Serum sickness.

[Non-Approvable Use] Ophthalmic Diseases* [14, A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation.

[Non-Approvable Use] Respiratory Diseases* [11, A] Symptomatic sarcoidosis

[Non-Approvable Use] Edematous State* [12, 13, 15, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Drug Name: Purified Cortrophin Gel (repository corticotropin injection)

Exacerbations of Multiple Sclerosis [4, 5] Indicated for acute exacerbations of multiple sclerosis.

All Other Disease States [A] *Please Note: The request for Purified Cortrophin Gel for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions.

[Non-Approvable Use] Rheumatic Disorders* [6, 7, A] Indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis; Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); Ankylosing spondylitis; Acute gouty arthritis.

[Non-Approvable Use] Collagen Diseases* [8-10, A] Indicated during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

[Non-Approvable Use] Dermatologic Diseases* [A] Indicated for severe erythema multiforme (Stevens-Johnson syndrome), severe psoriasis.

[Non-Approvable Use] Allergic States* [A] Indicated for atopic dermatitis, serum sickness.

[Non-Approvable Use] Ophthalmic Diseases* [14, A] Indicated for severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic

neuritis, chorioretinitis, anterior segment inflammation.

[Non-Approvable Use] Respiratory Diseases* [11, A] Indicated for symptomatic sarcoidosis.

[Non-Approvable Use] Edematous States* [12, 13, 15, A] Indicated to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Off Label Uses: Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

2 . Criteria

Product Name:Acthar Gel 80 unit/mL vial, Purified Cortrophin Gel [off-label]	
Diagnosis	Infantile Spasms (West Syndrome)
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
CORTROPHIN	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand

Approval Criteria

1 - Diagnosis of infantile spasms (West Syndrome)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Patient is less than 2 years of age

Product Name:Acthar Gel, Purified Cortrophin Gel	
Diagnosis	Multiple Sclerosis
Approval Length	3 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
CORTROPHIN	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 40 UNIT/0.5ML	3030001000D120	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 80 UNIT/ML	3030001000D130	Brand

Approval Criteria

1 - Diagnosis of acute exacerbation of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - One of the following:

3.1 Both of the following:

Patient is new to therapy with corticotropin

Trial and failure, contraindication, or intolerance to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone)

OR

3.2 All of the following:

Patient's multiple sclerosis exacerbations have been treated in the past with corticotropin

Patient has benefitted from treatment with corticotropin for acute exacerbations of multiple sclerosis

Medication is being used to treat a new exacerbation of multiple sclerosis

Product Name:Acthar Gel, Purified Cortrophin Gel	
Diagnosis	All Other Indications [A]
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
CORTROPHIN	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 40 UNIT/0.5ML	3030001000D120	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 80 UNIT/ML	3030001000D130	Brand

Approval Criteria

1 - The request for Acthar Gel and Purified Cortrophin Gel for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized and will not be approved. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions:

Rheumatic Disorders* [6, 7, A] As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis, Acute gouty arthritis.

Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome, Severe psoriasis.

Allergic States* [A] Serum sickness, Atopic dermatitis.

Ophthalmic Diseases* [14, A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation; Allergic conjunctivitis.

Respiratory Diseases* [11, A] Symptomatic sarcoidosis.

Edematous State* [12, 13, 15, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Any other disease state not mentioned [A]*

Notes	*Other disease states lack published clinical literature to support the use of Acthar or Purified Cortrophin Gel [A]

Product Name:Acthar Gel 80 unit/mL vial, Purified Cortrophin Gel [off-label]	
Diagnosis	Infantile Spasms (West Syndrome)
Approval Length	4 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
CORTROPHIN	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of infantile spasms (West Syndrome)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Patient is less than 2 years of age

Product Name:Acthar Gel 40 unit/0.5 mL auto-injector, Acthar gel 80 unit/mL auto-injector	
Diagnosis	Multiple Sclerosis
Approval Length	3 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 40 UNIT/0.5ML	3030001000D120	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 80 UNIT/ML	3030001000D130	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of acute exacerbation of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Both of the following:

Patient is new to therapy with corticotropin

Trial and failure, contraindication, or intolerance to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone)

OR

3.2 All of the following:

Patient's multiple sclerosis exacerbations have been treated in the past with corticotropin

Patient has benefitted from treatment with corticotropin for acute exacerbations of multiple sclerosis

Medication is being used to treat a new exacerbation of multiple sclerosis

Product Name:Acthar Gel 40 unit/0.5 mL auto-injector, Acthar gel 80 unit/mL auto-injector	
Diagnosis	All Other Indications [A]
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 40 UNIT/0.5ML	3030001000D120	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 80 UNIT/ML	3030001000D130	Brand

Approval Criteria

1 - The request for Acthar Gel and Purified Cortrophin Gel for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized and will not be approved. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions:

Rheumatic Disorders* [6, 7, A] As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis, Acute gouty arthritis.

Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis). Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome, Severe psoriasis. Allergic States* [A] Serum sickness, Atopic dermatitis. Ophthalmic Diseases* [14, A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation; Allergic conjunctivitis. Respiratory Diseases* [11, A] Symptomatic sarcoidosis. Edematous State* [12, 13, 15, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. Any other disease state not mentioned [A]*	
Notes	*Other disease states lack published clinical literature to support the use of Acthar or Purified Cortrophin Gel [A]

3 . Endnotes

Grandfathered indications, although briefly mentioned in the labeling, do not have clinical studies in the prescribing information or medical literature supporting their use of Acthar or Purified Cortrophin Gel.

4 . References

Acthar prescribing information. Mallinckrodt ARD LLC. Bedminster, NJ. June 2024.

Baram TZ, Mitchell WG, Tournay A, et al. High-dose corticotropin (ACTH) versus prednisone for infantile spasms: a prospective, randomized, blinded study. Pediatrics. 1996 Mar: 97(3):375-379.

Hrachovy RA, Frost JD, Glaze DG. High-dose, long-duration versus low-dose, short-duration corticotropin therapy for infantile spasms. J Pediatr. 1994 May; 124(5): 803-806.

Thompson, AJ. Relative efficacy of IV methylprednisolone vs ACTH in acute relapse of MS. Neurology. 1989 July;39(7):969.

Citterio A, La Mantia L, Ciucci G, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database of Systematic Reviews 2000, Issue 4.

Gillis T, Crane M, Hinkle C, et al. Repository corticotropin injection as adjunctive therapy in patients with rheumatoid arthritis who have failed previous therapies with at least three different modes of action. Open Access Rheumatol. 2017;9:131-138.

Brown, A. Repository corticotropin injection in patients with refractory psoriatic arthritis: a case series. Open Access Rheumatol. 2016;8:97-102.

Furie R, Mitrane M, Zhao E, et al. Efficacy and tolerability of repository corticotropin injection in patients with persistently active SLE: results of a phase 4, randomised, controlled pilot study. Lupus Sci Med. 2016;3(1):e000180.

Patel A, Seely G, Aggarwal R. Repository corticotropin injection for treatment of idiopathic inflammatory myopathies. Case Rep Rheumatol. 2016;2016:9068061.

Aggarwal R, Marder G, Koontz DC, et al. Efficacy and safety of adrenocorticotropic hormone gel in refractory dermatomyositis and polymyositis. Ann Rheum Dis. 2018 May;77(5):720-727.

Baughman RP, Sweiss N, Keijsers R, et al. Repository corticotropin for chronic pulmonary sarcoidosis. Lung. 2017;195(3):313-322.

Bomback AS, Tumlin JA, Baranski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. Drug Des Devel Ther. 2011;5:147-153.

Bomback AS, Canetta PA, Beck Jr LH, et al. Treatment of resistant glomerular diseases with adrenocorticotropic hormone gel: A prospective trial. Am J Nephrol 2012;36:58-67.

Sharon Y, Chu DS. Adrenocorticotropic hormone gel for patients with non-infectious uveitis. Am J Ophthalmol Case Rep. 2019;15:100502.

Madan A, Mojovic-Das S, Stankovic A, et al. Acthar gel in the treatment of nephrotic syndrome: a multicenter retrospective case series. BMC Nephrol. 2016;17:37.

Purified Cortrophin Gel prescribing information. ANI Pharmaceuticals, Inc. Baudette, MN. October 2023.

5 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233244
Guideline Name	Retevmo (selpercatinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	7/15/2020
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Retevmo (selpercatinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test. **Medullary Thyroid Cancer (MTC)** Indicated for the treatment of adults and pediatric patients 2 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy. **Thyroid Cancer** Indicated for the treatment of adults and pediatric patients 2 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). **Solid Tumors** Indicated for the treatment of adults and pediatric patients 2 years of age or older with locally advanced or metastatic solid tumors with a RET gene fusion, as detected by

an FDA-approved test, that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name:Retevmo Tablets, Retevmo Capsules	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETEVMO	SELPERCATINIB CAP 40 MG	21535779000120	Brand
RETEVMO	SELPERCATINIB CAP 80 MG	21535779000140	Brand
RETEVMO	SELPERCATINIB TAB 40 MG	21535779000320	Brand
RETEVMO	SELPERCATINIB TAB 80 MG	21535779000330	Brand
RETEVMO	SELPERCATINIB TAB 120 MG	21535779000340	Brand
RETEVMO	SELPERCATINIB TAB 160 MG	21535779000350	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

Locally Advanced

Metastatic

AND

3 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA) - approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Retevmo Tablets, Retevmo Capsules	
Diagnosis	Medullary Thyroid Cancer (MTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETEVMO	SELPERCATINIB CAP 40 MG	21535779000120	Brand
RETEVMO	SELPERCATINIB CAP 80 MG	21535779000140	Brand
RETEVMO	SELPERCATINIB TAB 40 MG	21535779000320	Brand
RETEVMO	SELPERCATINIB TAB 80 MG	21535779000330	Brand
RETEVMO	SELPERCATINIB TAB 120 MG	21535779000340	Brand
RETEVMO	SELPERCATINIB TAB 160 MG	21535779000350	Brand

Approval Criteria

1 - Diagnosis of medullary thyroid cancer (MTC)

AND

2 - Disease is ONE of the following:

Advanced

Metastatic

AND

3 - Patient is 2 years of age or older

AND

4 - Disease has presence of rearranged during transfection (RET) gene mutation tumor(s) as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Disease requires treatment with systemic therapy

Product Name:Retevmo Tablets, Retevmo Capsules	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETEVMO	SELPERCATINIB CAP 40 MG	21535779000120	Brand
RETEVMO	SELPERCATINIB CAP 80 MG	21535779000140	Brand
RETEVMO	SELPERCATINIB TAB 40 MG	21535779000320	Brand
RETEVMO	SELPERCATINIB TAB 80 MG	21535779000330	Brand
RETEVMO	SELPERCATINIB TAB 120 MG	21535779000340	Brand
RETEVMO	SELPERCATINIB TAB 160 MG	21535779000350	Brand

Approval Criteria

1 - Diagnosis of thyroid cancer

AND

2 - Disease is ONE of the following:

Advanced

Metastatic

AND

3 - Patient is 2 years of age or older

AND

4 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Disease requires treatment with systemic therapy

AND

6 - ONE of the following

Patient is radioactive iodine-refractory

Radioactive iodine therapy is not appropriate

Product Name:Retevmo Tablets, Retevmo Capsules	
Diagnosis	Solid Tumors
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETEVMO	SELPERCATINIB CAP 40 MG	21535779000120	Brand
RETEVMO	SELPERCATINIB CAP 80 MG	21535779000140	Brand
RETEVMO	SELPERCATINIB TAB 40 MG	21535779000320	Brand
RETEVMO	SELPERCATINIB TAB 80 MG	21535779000330	Brand
RETEVMO	SELPERCATINIB TAB 120 MG	21535779000340	Brand
RETEVMO	SELPERCATINIB TAB 160 MG	21535779000350	Brand

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Disease is ONE of the following:

Locally Advanced

Metastatic

AND

3 - Patient is 2 years of age or older

AND

4 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [A, 1]

AND

5 - ONE of the following:

Disease has progressed on or following prior systemic treatment (e.g., chemotherapy)

There are no satisfactory alternative treatment options

Product Name:Retevmo Tablets, Retevmo Capsules	
Diagnosis	Non-Small Cell Lung Cancer, Medullary Thyroid Cancer (MTC), Thyroid Cancer, Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETEVMO	SELPERCATINIB CAP 40 MG	21535779000120	Brand
RETEVMO	SELPERCATINIB CAP 80 MG	21535779000140	Brand
RETEVMO	SELPERCATINIB TAB 40 MG	21535779000320	Brand
RETEVMO	SELPERCATINIB TAB 80 MG	21535779000330	Brand
RETEVMO	SELPERCATINIB TAB 120 MG	21535779000340	Brand
RETEVMO	SELPERCATINIB TAB 160 MG	21535779000350	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

An FDA-approved companion diagnostic test for the detection of RET gene fusions and RET gene mutations in plasma or in tumors other than NSCLC and thyroid cancer is not currently available.

4 . References

Retevmo Prescribing Information. Lilly USA. Indianapolis, IN. September 2024.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-229155
Guideline Name	Retinal Vascular Disease Agents
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	
P&T Revision Date:	12/18/2024

1 . Indications

Drug Name: Beovu (brolucizumab)
Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of neovascular (wet) age-related macular degeneration (nAMD). **Diabetic Macular Edema (DME)** Indicated for the treatment of diabetic macular edema (DME).
Drug Name: Eylea (aflibercept)
Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of neovascular (wet) age-related macular degeneration (nAMD). **Macular Edema Following Retinal Vein Occlusion** Indicated for the treatment of patients with macular edema following retinal vein occlusion (RVO). **Diabetic Macular Edema** Indicated for the treatment of patients with diabetic macular edema

(DME).

Diabetic Retinopathy Indicated for the treatment of diabetic retinopathy (DR).

Retinopathy of Prematurity (ROP) Indicated for the treatment of retinopathy of prematurity (ROP).

Drug Name: Eylea HD (aflibercept)

Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of neovascular (wet) age-related macular degeneration (nAMD).

Diabetic Macular Edema Indicated for the treatment of patients with diabetic macular edema (DME).

Diabetic Retinopathy Indicated for the treatment of diabetic retinopathy (DR).

Drug Name: Lucentis 0.5mg (ranibizumab), Byooviz (ranibizumab-nuna), Cimerli 0.5mg (ranibizumab-eqrn)

Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD).

Macular Edema Following Retinal Vein Occlusion Indicated for the treatment of patients with macular edema following retinal vein occlusion (RVO).

Myopic Choroidal Neovascularization Indicated for the treatment of patients with myopic choroidal neovascularization (mCNV).

Drug Name: Lucentis 0.3 mg (ranibizumab), Cimerli 0.3mg (ranibizumab-eqrn)

Diabetic Macular Edema Indicated for the treatment of patients with diabetic macular edema (DME).

Diabetic Retinopathy Indicated for the treatment of diabetic retinopathy (DR).

Drug Name: Susvimo (ranibizumab)

Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD) who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor.

Drug Name: Vabysmo (faricimab-svoa)

Diabetic Macular Edema Indicated for the treatment of patients with diabetic macular edema (DME).

Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of

patients with neovascular (wet) age-related macular degeneration (nAMD).

Macular Edema Following Retinal Vein Occlusion Indicated for the treatment of patients with macular edema following retinal vein occlusion.

Drug Name: Pavblu (aflibercept-ayyh)

Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of neovascular (wet) age-related macular degeneration (nAMD).

Macular Edema Following Retinal Vein Occlusion Indicated for the treatment of patients with macular edema following retinal vein occlusion (RVO).

Diabetic Macular Edema Indicated for the treatment of patients with diabetic macular edema (DME).

Diabetic Retinopathy Indicated for the treatment of diabetic retinopathy (DR).

2 . Criteria

Product Name:Beovu, Vabysmo	
Diagnosis	Diabetic Macular Edema (DME), Neovascular (wet) age-related macular degeneration (nAMD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BEOVU	BROLUCIZUMAB-DBLL INTRAVITREAL SOLN 6 MG/0.05ML	86655025202020	Brand
VABYSMO	FARICIMAB-SVOA INTRAVITREAL INJ 6 MG/0.05ML (120 MG/ML)	86652522702020	Brand
BEOVU	BROLUCIZUMAB-DBLL INTRAVITREAL SOLN PREF SYRINGE 6 MG/0.05ML	8665502520E525	Brand
VABYSMO	FARICIMAB-SVOA INTRAVITREAL SOLN PREF SYR 6 MG/0.05ML	8665252270E520	Brand

Approval Criteria

1 - One of the following diagnoses:

Neovascular (wet) age-related macular degeneration (nAMD) [A]

Diabetic macular edema (DME)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Vabysmo	
Diagnosis	Macular Edema following Retinal Vein Occlusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VABYSMO	FARICIMAB-SVOA INTRAVITREAL INJ 6 MG/0.05ML (120 MG/ML)	86652522702020	Brand
VABYSMO	FARICIMAB-SVOA INTRAVITREAL SOLN PREF SYR 6 MG/0.05ML	8665252270E520	Brand

Approval Criteria

1 - Diagnosis of macular edema following retinal vein occlusion

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Lucentis 0.3mg	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUCENTIS	RANIBIZUMAB INTRAVITREAL SOLN PREF SYR 0.3 MG/0.05ML	8665506000E510	Brand
LUCENTIS	RANIBIZUMAB INTRAVITREAL INJ 0.3 MG/0.05ML (6 MG/ML)	86655060002012	Brand

Approval Criteria

1 - One of the following diagnoses:

Diabetic macular edema (DME)

Diabetic retinopathy (DR)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Byooviz, Lucentis 0.5mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUCENTIS	RANIBIZUMAB INTRAVITREAL SOLN PREF SYR 0.5 MG/0.05ML	8665506000E520	Brand
LUCENTIS	RANIBIZUMAB INTRAVITREAL INJ 0.5 MG/0.05ML (10 MG/ML)	86655060002020	Brand
BYOOVIZ	RANIBIZUMAB-NUNA INTRAVITREAL INJ 0.5 MG/0.05ML (10 MG/ML)	86655060502020	Brand

Approval Criteria

1 - One of the following diagnoses:

Neovascular (wet) age-related macular degeneration (nAMD) [A]

Macular edema following retinal vein occlusion (RVO)

Myopic choroidal neovascularization (mCNV)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Cimerli 0.3mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMERLI	RANIBIZUMAB-EQRN INTRAVITREAL INJ 0.3 MG/0.05ML (6 MG/ML)	86655060302012	Brand

Approval Criteria

1 - One of the following diagnoses:

Diabetic macular edema (DME)

Diabetic retinopathy (DR)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Cimerli 0.5mg

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CIMERLI	RANIBIZUMAB-EQRN INTRAVITREAL INJ 0.5 MG/0.05ML (10 MG/ML)	86655060302020	Brand

Approval Criteria

1 - One of the following diagnoses:

Neovascular (wet) age-related macular degeneration (nAMD) [A]

Macular edema following retinal vein occlusion (RVO)

Myopic choroidal neovascularization (mCNV)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Eylea, Pavblu	
Diagnosis	Neovascular (Wet) Age-Related Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Diabetic Macular Edema, Diabetic Retinopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EYLEA	AFLIBERCEPT INTRAVITREAL SOLN PREF SYR 2 MG/0.05ML	8665501000E520	Brand
EYLEA	AFLIBERCEPT INTRAVITREAL INJ 2 MG/0.05ML (40 MG/ML)	86655010002020	Brand

PAVBLU	AFLIBERCEPT-AYYH INTRAVITREAL SOLN PREF SYR 2 MG/0.05ML	8665501014E520	Brand
PAVBLU	AFLIBERCEPT-AYYH INTRAVITREAL INJ 2 MG/0.05ML (40 MG/ML)	86655010142020	Brand

Approval Criteria

1 - One of the following diagnoses:

Neovascular (wet) age-related macular degeneration (nAMD) [A]

Macular edema following retinal vein occlusion (RVO)

Diabetic macular edema (DME)

Diabetic retinopathy (DR)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Eylea, Pavblu	
Diagnosis	Neovascular (Wet) Age-Related Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Diabetic Macular Edema, Diabetic Retinopathy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EYLEA	AFLIBERCEPT INTRAVITREAL SOLN PREF SYR 2 MG/0.05ML	8665501000E520	Brand
EYLEA	AFLIBERCEPT INTRAVITREAL INJ 2 MG/0.05ML (40 MG/ML)	86655010002020	Brand
PAVBLU	AFLIBERCEPT-AYYH INTRAVITREAL SOLN PREF SYR 2 MG/0.05ML	8665501014E520	Brand
PAVBLU	AFLIBERCEPT-AYYH INTRAVITREAL INJ 2 MG/0.05ML (40 MG/ML)	86655010142020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., Improvement in Best Corrected Visual Acuity (BCVA) compared to baseline, stable vision)

Product Name:Eylea Injectable Vial	
Diagnosis	Retinopathy of Prematurity (ROP) [2, C]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EYLEA	AFLIBERCEPT INTRAVITREAL INJ 2 MG/0.05ML (40 MG/ML)	86655010002020	Brand

Approval Criteria

1 - Diagnosis of retinopathy of prematurity (ROP)

AND

2 - ONE of the following: [2]

Patient gestational age at birth less than or equal to 32 weeks [D]

Patient birth weight less than or equal to 1500 grams

AND

3 - Patient weight greater than 800 grams on day of treatment [2]

AND

4 - Retinopathy of prematurity (ROP) is present in at least one eye with one of the following classifications: [2, E-H]

ROP zone 1, stage 1 plus, 2 plus, 3, or 3 plus

ROP zone 2, stage 2 plus or 3 plus

AP - ROP (aggressive posterior ROP)

AND

5 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases [I, 13 -14]

Product Name:Eylea Injectable Vial	
Diagnosis	Retinopathy of Prematurity (ROP) [2, C]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EYLEA	AFLIBERCEPT INTRAVITREAL INJ 2 MG/0.05ML (40 MG/ML)	86655010002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by the absence of active ROP and unfavorable structural outcomes (e.g., retinal detachment, macular dragging, macular fold, retrolental opacity) [2]

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases [I, 13 -14]

Product Name:Eylea HD	
Diagnosis	Neovascular (Wet) Age-Related Macular Degeneration, Diabetic Macular Edema, Diabetic Retinopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EYLEA HD	AFLIBERCEPT INTRAVITREAL INJ 8 MG/0.07ML (114.3 MG/ML)	86655010002080	Brand

Approval Criteria

1 - One of the following diagnoses:

Neovascular (wet) age-related macular degeneration (nAMD) [A]

Diabetic macular edema (DME)

Diabetic retinopathy (DR)

AND

2 - Trial and failure, or intolerance to Eylea

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Eylea HD	
Diagnosis	Neovascular (Wet) Age-Related Macular Degeneration, Diabetic Macular Edema, Diabetic Retinopathy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EYLEA HD	AFLIBERCEPT INTRAVITREAL INJ 8MG/0.07ML (114.3MG/ML)	86655010002080	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., Improvement in Best Corrected Visual Acuity (BCVA) compared to baseline, stable vision)

AND

2 - Trial and failure, or intolerance to Eylea

Product Name:Susvimo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUSVIMO	RANIBIZUMAB INTRAVITREAL (IMPLANT 1ST FILL) INJ 10 MG/0.1ML	86655060002040	Brand
SUSVIMO	RANIBIZUMAB INTRAVITREAL (IMPLANT REFILL) INJ 10 MG/0.1ML	86655060002042	Brand
SUSVIMO OCULAR IMPLANT	*OCULAR IMPLANT - INTRAVITREAL RESERVOIR**	97604040002340	Brand

Approval Criteria

1 - Diagnosis of neovascular (wet) age-related macular degeneration (nAMD) [A]

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Beovu, Byooviz, Cimerli, Lucentis, Susvimo, Vabysmo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LUCENTIS	RANIBIZUMAB INTRAVITREAL SOLN PREF SYR 0.3 MG/0.05ML	8665506000E510	Brand
LUCENTIS	RANIBIZUMAB INTRAVITREAL SOLN PREF SYR 0.5 MG/0.05ML	8665506000E520	Brand
LUCENTIS	RANIBIZUMAB INTRAVITREAL INJ 0.3 MG/0.05ML (6 MG/ML)	86655060002012	Brand
LUCENTIS	RANIBIZUMAB INTRAVITREAL INJ 0.5 MG/0.05ML (10 MG/ML)	86655060002020	Brand
BEOVU	BROLUCIZUMAB-DBLL INTRAVITREAL SOLN 6 MG/0.05ML	86655025202020	Brand
VABYSMO	FARICIMAB-SVOA INTRAVITREAL INJ 6 MG/0.05ML (120 MG/ML)	86652522702020	Brand
SUSVIMO	RANIBIZUMAB INTRAVITREAL (IMPLANT 1ST FILL) INJ 10 MG/0.1ML	86655060002040	Brand
SUSVIMO	RANIBIZUMAB INTRAVITREAL (IMPLANT REFILL) INJ 10 MG/0.1ML	86655060002042	Brand
SUSVIMO OCULAR IMPLANT	*OCULAR IMPLANT - INTRAVITREAL RESERVOIR**	97604040002340	Brand
BEOVU	BROLUCIZUMAB-DBLL INTRAVITREAL SOLN PREF SYRINGE 6 MG/0.05ML	8665502520E525	Brand
BYOOVIZ	RANIBIZUMAB-NUNA INTRAVITREAL INJ 0.5 MG/0.05ML (10 MG/ML)	86655060502020	Brand
CIMERLI	RANIBIZUMAB-EQRN INTRAVITREAL INJ 0.3 MG/0.05ML (6 MG/ML)	86655060302012	Brand
CIMERLI	RANIBIZUMAB-EQRN INTRAVITREAL INJ 0.5 MG/0.05ML (10 MG/ML)	86655060302020	Brand
VABYSMO	FARICIMAB-SVOA INTRAVITREAL SOLN PREF SYR 6 MG/0.05ML	8665252270E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., Improvement in Best Corrected Visual Acuity (BCVA) compared to baseline, stable vision)

3 . Definitions

Definition	Description
Retinopathy of Prematurity (ROP)	Retinopathy of prematurity (ROP) is a developmental vascular proliferative disorder that occurs in the retina of preterm infants with incomplete retinal vascularization. ROP is an important cause of severe visual impairment in childhood. [11]

4 . Endnotes

Neovascular Age-Related Macular Degeneration (nAMD) may also be referred to as wet or exudative AMD. [1]

Congress established the 503(B) facilities to provide compounded pharmaceuticals for office use without a prescription. 503(B) Outsourcing Facilities are compounding pharmacies that must meet higher federal safety, sterility, and quality control standards. [4,5]

Each sterile vial should only be used for the treatment of a single eye. Do not use the EYLEA pre-filled syringe for the treatment of ROP. [2]

Gestational age: The length of time between a baby's conception and birth. [10]

How serious the ROP is depends on what part of the eye is affected (the zone); how far the disease has progressed (the stage); and whether the blood vessels themselves are markedly abnormal (plus disease). Stages 1 and 2 are considered mild; Stages 3-5 are increasingly serious. [10]

Zone 1: This represents the least amount of retinal vascular development and includes retinal vascularization limited to a circular area centered around the optic nerve. Zone I ROP is a strong predictor for severe ROP. Zone 2: Vascularization limited to the circular area outside zone I with the optic nerve as the center. Zone 3: Vascularization within the remaining temporal, crescent-shaped area. Once vascularization extends to the nasal ora serrata and into zone III, there is little risk of a poor visual outcome from ROP. [11]

Plus disease. Defined as two quadrants of dilated and tortuous vessels and is a strong predictor of severe ROP. [11]

Stage 1. A demarcation line between vascularized and avascular retina. Stage 2. A ridge with volume in the region of the demarcation line. Stage 3. Neovascularization growing into the vitreous at the ridge. Stage 3 is a strong predictor of severe ROP and a poor outcome. Stage 4. A partial retinal detachment. Treatment of progressive stage 4 ROP can preserve and improve visual outcomes by preventing stage 5 ROP. Stage 4 is further classified by whether the macula is involved (4A without macular involvement and 4B with macular involvement) and by whether it is predominantly exudative or tractional. Exudative ROP that occurs after treatment with laser or cryotherapy may resolve spontaneously. Stage 5. Total retinal detachment. [11]

Examinations for ROP should be performed by an ophthalmologist who is experienced in the examination of preterm infants for ROP using a binocular indirect ophthalmoscope. Pediatric ophthalmology and retina fellows are less adept than experienced attending ophthalmologists at identifying clinically significant ROP when examining digital images. [13, 14]

Eylea HD contains a higher molar dose of aflibercept designed to allow for longer dosing intervals between treatments. [16]

5 . References

Beovu Prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. May 2022.

Eylea Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. February 2023.

Lucentis Prescribing information. Genentech, Inc. South San Francisco, CA. October 2020.

FDA Final Guidance on Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Guidance for Industry. January 2018. Available at: https://www.fda.gov/media/90986/download. Accessed April 7,2021.

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Vabysmo Prescribing information. Genentech, Inc. South San Francisco, CA. October 2023.

Byooviz Prescribing Information. Biogen, Inc. Cambridge, MA. April 2022.

Cimerli Prescribing Information. Coherus BioSciences, Inc. Redwood City, CA. August 2022.

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Hartnett, M. Managing Retinopathy of Prematurity. Available at: https://www.aao.org/eyenet/article/managing-retinopathy-of-prematurity. Accessed February 28, 2023.

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Wong, R., Ventura, C. et al. Training fellows for retinopathy of prematurity care: A Web-based survey. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3338950/. Accessed March 14, 2023.

Eylea HD Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. August 2023.

Eylea Healthcare Professionals website. Available at: https://eyleahcp.us/s/. Accessed September 26, 2023.

Pavblu Prescribing information. Amgen, Inc. Thousand Oaks, CA. August 2024.

6 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228950
Guideline Name	Revcovi (elapegademase-lvlr)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Revcovi (elapegademase-lvlr)
Adenosine deaminase severe combined immune deficiency (ADA-SCID) Indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.

2 . Criteria

Product Name:Revcovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVCOVI	ELAPEGADEMASE-LVLR IM SOLN 2.4 MG/1.5ML (1.6 MG/ML)	30902030202020	Brand

Approval Criteria

1 - Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID)

Product Name:Revcovi	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVCOVI	ELAPEGADEMASE-LVLR IM SOLN 2.4 MG/1.5ML (1.6 MG/ML)	30902030202020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

Revcovi Prescribing Information. Chiesi USA, Inc. Cary, NC 27518. August 2022

Immune Deficiency Foundation Patient & Family Handbook for Primary Immunodeficiency Diseases. Fifth Edition. 2013.

4 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Revlimid (lenalidomide)

Prior Authorization Guideline

Guideline ID	GL-228952
Guideline Name	Revlimid (lenalidomide)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Revlimid (lenalidomide)
Myelodysplastic Syndromes Indicated for the treatment of adult patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A] **Multiple Myeloma** In combination with dexamethasone is indicated for the treatment of adult patients with multiple myeloma (MM). Also indicated as maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A] **Mantle Cell Lymphoma (MCL)** Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A] **Follicular Lymphoma (FL)** Revlimid in combination with a rituximab product, is indicated for

the treatment of adult patients with previously treated follicular lymphoma (FL). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]

Marginal Zone Lymphoma (MZL) Revlimid in combination with a rituximab product, is indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]

2 . Criteria

Product Name:Brand Revlimid, Generic lenalidomide	
Diagnosis	Myelodysplastic Syndromes, Multiple Myeloma, Mantle Cell Lymphoma, Follicular Lymphoma, Marginal Zone Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVLIMID	LENALIDOMIDE CAP 5 MG	99394050000120	Brand
REVLIMID	LENALIDOMIDE CAP 10 MG	99394050000130	Brand
REVLIMID	LENALIDOMIDE CAP 15 MG	99394050000140	Brand
REVLIMID	LENALIDOMIDE CAP 25 MG	99394050000150	Brand
REVLIMID	LENALIDOMIDE CAPS 2.5 MG	99394050000110	Brand
REVLIMID	LENALIDOMIDE CAP 20 MG	99394050000145	Brand
LENALIDOMIDE	LENALIDOMIDE CAP 5 MG	99394050000120	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 10 MG	99394050000130	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 15 MG	99394050000140	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 25 MG	99394050000150	Generic
LENALIDOMIDE	LENALIDOMIDE CAPS 2.5 MG	99394050000110	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 20 MG	99394050000145	Generic

Approval Criteria

1 - Diagnosis of ONE of the following:

1.1 Symptomatic or transfusion-dependent anemia due to myelodysplastic syndrome (MDS) associated with a deletion 5q abnormality [2]

OR

1.2 Multiple Myeloma

OR

1.3 Relapsed or progressed mantle cell lymphoma (MCL)

OR

1.4 Follicular lymphoma (FL) that has been previously treated

OR

1.5 Marginal zone lymphoma (MZL) that has been previously treated

Product Name:Brand Revlimid, Generic lenalidomide	
Diagnosis	Myelodysplastic Syndromes, Multiple Myeloma, Mantle Cell Lymphoma, Follicular Lymphoma, Marginal Zone Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVLIMID	LENALIDOMIDE CAP 5 MG	99394050000120	Brand
REVLIMID	LENALIDOMIDE CAP 10 MG	99394050000130	Brand
REVLIMID	LENALIDOMIDE CAP 15 MG	99394050000140	Brand
REVLIMID	LENALIDOMIDE CAP 25 MG	99394050000150	Brand

REVLIMID	LENALIDOMIDE CAPS 2.5 MG	99394050000110	Brand
REVLIMID	LENALIDOMIDE CAP 20 MG	99394050000145	Brand
LENALIDOMIDE	LENALIDOMIDE CAP 5 MG	99394050000120	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 10 MG	99394050000130	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 15 MG	99394050000140	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 25 MG	99394050000150	Generic
LENALIDOMIDE	LENALIDOMIDE CAPS 2.5 MG	99394050000110	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 20 MG	99394050000145	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

Although the prescribing information for Revlimid states that it is not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials due to the increased risk of mortality, current NCCN practice guideline still recommends single agent lenalidomide or in combination with rituximab for relapsed/refractory CLL. [1, 2]

4 . References

Revlimid Prescribing Information. Celgene Corporation. Princeton, NJ. March 2023.

National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available by subscription at: www.nccn.org. Accessed March 8, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228716
Guideline Name	Reyvow (lasmiditan) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Reyvow (lasmiditan)
Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Reyvow is not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name:Reyvow	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REYVOW	LASMIDITAN SUCCINATE TAB 50 MG	67406540600310	Brand
REYVOW	LASMIDITAN SUCCINATE TAB 100 MG	67406540600320	Brand

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient has less than 15 headache days per month [2]

AND

4 - Patient is 18 years of age or older [A]

AND

5 - One of the following: [3]

Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)

Contraindication to all triptans

AND

6 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [B, 3]:

Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

A beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

Atacand (candesartan) unless there is a contraindication or intolerance to this medication

Generic lisinopril unless there is a contraindication or intolerance to this medication

AND

7 - Will not be used concomitantly with central nervous system (CNS) depressants (e.g., alprazolam, phenobarbital, alcohol)

AND

8 - Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 8 hours after taking each dose of Reyvow

AND

9 - Trial and failure, contraindication, or intolerance to two of the following:

Nurtec

Ubrelvy

Zavzpret

Product Name:Reyvow	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REYVOW	LASMIDITAN SUCCINATE TAB 50 MG	67406540600310	Brand
REYVOW	LASMIDITAN SUCCINATE TAB 100 MG	67406540600320	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Will not be used for preventive treatment of migraine

AND

3 - Trial and failure, contraindication, or intolerance to two of the following:

Nurtec

Ubrelvy

Zavzpret

Product Name:Reyvow	
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
REYVOW	LASMIDITAN SUCCINATE TAB 50 MG	67406540600310	Brand
REYVOW	LASMIDITAN SUCCINATE TAB 100 MG	67406540600320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has less than 15 headache days per month [2]

AND

4 - Patient is 18 years of age or older [A]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [3]

Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)

Contraindication to all triptans

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, patient must be currently treated with one of the following: [B, 3]:

Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

A beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

Atacand (candesartan) unless there is a contraindication or intolerance to this medication

Generic lisinopril unless there is a contraindication or intolerance to this medication

AND

7 - Will not be used concomitantly with central nervous system (CNS) depressants (e.g., alprazolam, phenobarbital, alcohol)

AND

8 - Submission of medical records (e.g., chart notes) confirming that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 8 hours after taking each dose of Reyvow

AND

9 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

Nurtec

Ubrelvy

Zavzpret

3 . Endnotes

The safety and effectiveness in pediatric patients has not been established [1].

The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], and beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol] [4].

4 . References

Reyvow Prescribing Information. Lilly USA, LLC. Indianapolis , IN. September 2022.

Goadsby PJ, Wietecha LA, Dennehy EB, et al. Phase 3 randomized, placebo-controlled, double-blind study of lasmiditan for acute treatment of migraine. Brain. 2019 Jul 1;142(7):1894-1904.

AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.

Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26.

Prior Authorization Guideline

Guideline ID	GL-233284
Guideline Name	Rezdiffra (resmetirom) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/15/2024
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Rezdiffra (resmetirom)
Nonalcoholic steatohepatitis (NASH) Indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Limitations of Use: Avoid use of Rezdiffra in patients with decompensated cirrhosis.

2 . Criteria

Product Name:Rezdiffra	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REZDIFFRA	RESMETIROM 60 MG TAB	52601060000320	Brand
REZDIFFRA	RESMETIROM 80 MG TAB	52601060000330	Brand
REZDIFFRA	RESMETIROM 100 MG TAB	52601060000340	Brand

Approval Criteria

1 - Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH)

AND

2 - Patient does not have cirrhosis (e.g., decompensated cirrhosis)

AND

3 - Submission of medical records (e.g., chart notes) confirming disease is fibrosis stage F2 or F3 as confirmed by one of the following: [4]

3.1 Both of the following:

Serum biomarker [e.g., enhanced liver fibrosis (ELF) test, fibrosis-4 index (FIB-4)]

Imaging biomarker [e.g., FibroScan, magnetic resonance imaging-proton density fat fraction (MRI-PDFF)]

OR

3.2 One of the following:

FibroScan aspartate aminotransferase (FAST)

MRI aspartate aminotransferase (MAST)

Magnetic Resonance Elastography combined with fibrosis-4 index (MEFIB)

Liver biopsy within the past 12 months

AND

4 - Presence of greater than or equal to 3 metabolic risk factors (e.g., Type 2 diabetes, hypertension, obesity) [3]

AND

5 - Submission of medical records (e.g., chart notes) confirming drug is used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community based program)

AND

6 - Prescribed by or in consultation with one of the following:

Gastroenterologist

Hepatologist

Product Name:Rezdiffra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REZDIFFRA	RESMETIROM 60 MG TAB	52601060000320	Brand
REZDIFFRA	RESMETIROM 80 MG TAB	52601060000330	Brand

REZDIFFRA	RESMETIROM 100 MG TAB	52601060000340	Brand

Approval Criteria

1 - Patient demonstrates positive response to therapy (e.g., NASH resolution, fibrosis stage improvement, etc.)

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will continue to be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community based program)

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has not progressed to cirrhosis

Product Name:Rezdiffra	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
REZDIFFRA	RESMETIROM 60 MG TAB	52601060000320	Brand
REZDIFFRA	RESMETIROM 80 MG TAB	52601060000330	Brand
REZDIFFRA	RESMETIROM 100 MG TAB	52601060000340	Brand

Approval Criteria

1 - Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH)

AND

2 - Patient does not have cirrhosis (e.g., decompensated cirrhosis)

AND

3 - Submission of medical records (e.g., chart notes) confirming disease is fibrosis stage F2 or F3 as confirmed by one of the following: [4]

3.1 Both of the following:

Serum biomarker [e.g., enhanced liver fibrosis (ELF) test, fibrosis-4 index (FIB-4)]

Imaging biomarker [e.g., FibroScan, magnetic resonance imaging-proton density fat fraction (MRI-PDFF)]

OR

3.2 One of the following:

FibroScan aspartate aminotransferase (FAST)

MRI aspartate aminotransferase (MAST)

Magnetic Resonance Elastography combined with fibrosis-4 index (MEFIB)

Liver biopsy within the past 12 months

AND

4 - Presence of greater than or equal to 3 metabolic risk factors (e.g., Type 2 diabetes, hypertension, obesity)

AND

5 - Submission of medical records (e.g., chart notes) confirming drug is used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community based program)

AND

6 - Prescribed by or in consultation with one of the following:

Gastroenterologist

Hepatologist

3 . References

Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD practice guidance on the clinical assessment and management of nonalcoholic fatty liver disease.

Rezdiffra Prescribing Information. Madrigal Pharmaceuticals. West Conshohocken, PA. March 2024.

Harrison SA, Bedossa P, Guy CD, et al. A Phase 3, Randomized, Controlled Trial of Resmetirom in NASH with Liver Fibrosis. The New England Journal of Medicine. 2024;390(6):497-509.

Noureddin, Mazen et al. Expert Panel Recommendations: Practical Clinical Applications for Initiating and Monitoring Resmetirom in Patients with MASH/NASH and Moderate to Noncirrhotic Advanced Fibrosis.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228517
Guideline Name	Rezlidhia (olutasidenib) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rezlidhia (olutasidenib)
Acute Myeloid Leukemia (AML) Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

2 . Criteria

Product Name:Rezlidhia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REZLIDHIA	OLUTASIDENIB CAP 150 MG	21534960000120	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Disease is one of the following:

Relapsed

Refractory

AND

3 - Presence of a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to Tibsovo (ivosidenib)

OR

4.2 For continuation of prior therapy

Product Name:Rezlidhia	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REZLIDHIA	OLUTASIDENIB CAP 150 MG	21534960000120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Tibsovo (ivosidenib)

OR

2.2 For continuation of prior therapy

Product Name:Rezlidhia	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
REZLIDHIA	OLUTASIDENIB CAP 150 MG	21534960000120	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Disease is one of the following:

Relapsed

Refractory

AND

3 - Presence of a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Tibsovo (ivosidenib)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy, defined as no more than a 45-day gap in therapy

3 . References

Rezlidhia Prescribing Information. Rigel Pharmaceuticals, Inc. South San Francisco, CA. December 2022.

The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on January 5, 2024.

Prior Authorization Guideline

Guideline ID	GL-228520
Guideline Name	Rezurock (belumosudil) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rezurock (belumosudil)
Chronic graft-versus-host disease Indicated for the treatment of chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients 12 years and older.

2 . Criteria

Product Name:Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REZUROCK	BELUMOSUDIL MESYLATE TAB 200 MG	99398510500320	Brand

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)

AND

3 - Patient is 12 years of age or older

Product Name:Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REZUROCK	BELUMOSUDIL MESYLATE TAB 200 MG	99398510500320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Rezurock	
Diagnosis	Chronic graft-versus-host disease

Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
REZUROCK	BELUMOSUDIL MESYLATE TAB 200 MG	99398510500320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of chronic graft-versus-host disease

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure of three or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)(2)

AND

3 - Patient is 12 years of age or older

Product Name:Rezurock	
Diagnosis	Chronic graft-versus-host disease - Twice daily (BID) Therapy
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
REZUROCK	BELUMOSUDIL MESYLATE TAB 200 MG	99398510500320	Brand

Approval Criteria

1 - Patient is using medication concomitantly with one of the following:

Strong CYP3A inducer (e.g., carbamazepine, phenobarbital, phenytoin, rifampin)

Proton pump inhibitor (e.g., omeprazole, pantoprazole, lansoprazole)

3 . References

Rezurock Prescribing Information. Kadmon Pharmaceuticals, LLC. Warrendale, PA. April 2024.

Cutler C, Lee SJ, Arai S, et al. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study [published correction appears in Blood. 2022 Mar 17;139(11):1772. doi: 10.1182/blood.2022015598]. Blood. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021

Prior Authorization Guideline

Guideline ID	GL-228718
Guideline Name	Rezzayo (rezafungin)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rezzayo (rezafungin)
Candidemia and invasive candidiasis Indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data for Rezzayo. Limitations of Use Rezzayo has not been studied in patients with endocarditis, osteomyelitis, and meningitis due to Candida.

2 . Criteria

Product Name:Rezzayo	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REZZAYO	REZAFUNGIN ACETATE FOR IV SOLN 200 MG (BASE EQUIVALENT)	11500070102120	Brand

Approval Criteria

1 - Diagnosis of candidemia or invasive candidiasis with limited or no alternative options

AND

2 - Patient is 18 years of age or older

AND

3 - Trial and failure, contraindication or intolerance to one of the following [2]:

generic caspofungin

generic micafungin

3 . References

Rezzayo Prescribing Information. Melinta Therapeutics LLC. Lincolnshire, IL. June 2023.

Peter G. Pappas, Carol A. Kauffman, David R. Andes, Cornelius J. Clancy, Kieren A. Marr, Luis Ostrosky-Zeichner, Annette C. Reboli, Mindy G. Schuster, Jose A. Vazquez, Thomas J. Walsh, Theoklis E. Zaoutis, Jack D. Sobel, Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America, Clinical Infectious Diseases, Volume 62, Issue 4, 15 February 2016, Pages e1–e50, https://doi.org/10.1093/cid/civ933

Prior Authorization Guideline

Guideline ID	GL-228957
Guideline Name	Riluzole Products - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Exservan (riluzole film), Rilutek (riluzole tablets), Tiglutik (riluzole suspension), Teglutik (riluzole suspension)
Amyotrophic Lateral Sclerosis (ALS) Indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS).

2 . Criteria

Product Name:Brand Rilutek, Teglutik, Tiglutik	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RILUTEK	RILUZOLE TAB 50 MG	74503070000320	Brand
TIGLUTIK	RILUZOLE SUSP 50 MG/10ML	74503070001820	Brand
TEGLUTIK	RILUZOLE SUSP 50 MG/10ML	74503070001820	Brand

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Trial and failure or intolerance to generic riluzole tablets

Product Name:Exservan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EXSERVAN	RILUZOLE ORAL FILM 50 MG	74503070008220	Brand

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Trial and failure or intolerance to both of the following:

generic riluzole tablets

Tiglutik suspension or Teglutik suspension

Product Name:Exservan	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EXSERVAN	RILUZOLE ORAL FILM 50 MG	74503070008220	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with both of the following formulary alternatives that have the same active ingredients:

generic riluzole tablets

Tiglutik suspension or Teglutik suspension

AND

3 - Submission of medical records confirming the formulary alternatives have not been effective and valid clinical rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternatives have not been shown to be effective despite having the same active ingredient

3 . References

Rilutek Prescribing Information. Covis Pharma. Zug, Switzerland. March 2020.

Tiglutik Prescribing Information. ITF Pharma, Inc. Berwyn, PA. April 2021.

Exservan Prescribing Information. Aquestive Therapeutics. Warren, NJ. April 2021.

Teglutik Prescribing Information. ITF Pharma, Inc. Berwyn, PA. February 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228958
Guideline Name	Rinvoq (upadacitinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rinvoq (upadacitinib) extended-release (ER) tablets
Rheumatoid Arthritis (RA) Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. **Non-radiographic Axial Spondyloarthritis (nr-AxSpA)** Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

Atopic Dermatitis (AD) Indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Crohn's Disease (CD) Indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.

Drug Name: Rinvoq (upadacitinib) ER tablets, Rinvoq LQ (upadacitinib) oral solution

Psoriatic Arthritis (PsA) Indicated for the treatment of adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq/Rinvoq LQ in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

Polyarticular Juvenile Idiopathic Arthritis (PJIA) Indicated for the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq/Rinvoq LQ in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

2 . Criteria

Product Name:Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

methotrexate

leflunomide

sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq, Rinvoq LQ	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

RINVOQ LQ	UPADACITINIB ORAL SOLN 1 MG/ML	66603072002020	Brand

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

leflunomide

methotrexate

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, etanercept)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq/Rinvoq LQ may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq, Rinvoq LQ	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ LQ	UPADACITINIB ORAL SOLN 1 MG/ML	66603072002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq/Rinvoq LQ may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq, Rinvoq LQ	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ LQ	UPADACITINIB ORAL SOLN 1 MG/ML	66603072002020	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [5]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq/Rinvoq LQ may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq, Rinvoq LQ	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ LQ	UPADACITINIB ORAL SOLN 1 MG/ML	66603072002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq/Rinvoq LQ may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq

Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 6]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 6]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., certolizumab pegol)

AND

6 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 6]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq

Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 45 MG	66603072007540	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [7, 8]:

Frequent diarrhea and abdominal pain

At least 10% weight loss

Complications such as obstruction, fever, abdominal mass

Abnormal lab values (e.g., C-reactive protein [CRP])

CD Activity Index (CDAI) greater than 220

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [7, 8]:

6-mercaptopurine

Azathioprine

Corticosteroids (e.g., prednisone)

Methotrexate

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for CD, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Crohn's disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 45 MG	66603072007540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 7, 8]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

AND

2 - Not used in combination with other JAK inhibitors, biological therapies for CD, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 45 MG	66603072007540	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [9, 10]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, ESR, CRP)

Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [9, 10]:

6-mercaptopurine

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

Azathioprine

Corticosteroids (e.g., prednisone)

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, golimumab)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhale d corticosteroids, and/or low stable dosages of oral corticosteroids (eq uivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 45 MG	66603072007540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 9, 10]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

AND

2 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhale d corticosteroids, and/or low stable dosages of oral corticosteroids (eq uivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Atopic Dermatitis (AD)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is 12 years of age or older

AND

3 - One of the following:

Involvement of at least 10% body surface area (BSA)

SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

4 - Prescribed by or in consultation with one of the following:

Dermatologist

Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following:

Medium or higher potency topical corticosteroid

Pimecrolimus cream

Tacrolimus ointment

Eucrisa (crisaborole) ointment

AND

6 - One of the following:

6.1 Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.)

OR

6.2 Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies:

Adbry (tralokinumab-ldrm)

Dupixent (dupilumab)

AND

7 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by at least ONE of the following:

Reduction in body surface area involvement from baseline

Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

AND

2 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [11]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05

	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2

	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05

4 . Endnotes

The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [12, 13] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [14]

5 . References

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6 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228961
Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rituxan Hycela (rituximab and hyaluronidase human)
Follicular Lymphoma Indicated for the treatment of adult patients with: 1) Relapsed or refractory, follicular lymphoma as a single agent 2) Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy 3) Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions. **Diffuse Large B-cell Lymphoma** Indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions. **Chronic Lymphocytic Leukemia (CLL)** Indicated for the treatment of adult patients with

previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC). Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

2 . Criteria

Product Name:Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Diagnosis of follicular lymphoma

AND

2 - One of the following:

2.1 Disease is relapsed or refractory

OR

2.2 Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy

OR

2.3 Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

OR

2.4 Both of the following:

2.4.1 Disease is previously untreated

AND

2.4.2 Medication is used in combination with first-line chemotherapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

Product Name:Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Diffuse Large B-cell Lymphoma
Approval Length	12 months [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Diagnosis of diffuse large B-cell lymphoma

AND

2 - Disease is previously untreated

AND

3 - Medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy

AND

4 - One of the following:

4.1 Trial and failure, or intolerance to Ruxience

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

Product Name:Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 months [B]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia

AND

2 - Medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

3 . Endnotes

Treatment for DLBCL consists of up to 8 cycles of 21 days each, a total duration of 6 months [1,3]. There is little evidence that use of rituximab as continuation therapy following R-CHOP induction provides additional benefit above induction alone. [2] This is in contrast with follicular lymphoma, where evidence does support maintenance [4] therapy and NCCN recommends consolidation with rituximab monotherapy [3]. However, to account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.

Treatment for CLL consists of up to 6 cycles of 28 days each, a total duration of 6 months [1]. To account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.

An FDA-approved biosimilar is an appropriate substitute for rituximab. [3]

The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [4]

4 . References

Rixtuan Hycela Prescribing Information. Genentech, Inc. South San Francisco, CA. June 2021.

Habermann TM, Weller EA, Morrison VA, et al. Rituximab-CHOP versus CHOP alone or with maintenance rituximab in older patients with diffuse large B-cell lymphoma. J Clin Oncol. 2006;24(19):3121-3127.

The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 25, 2024.

Salles G, Seymour JF, Lopez-Guillermo A, et al. Rituximab maintenance for 2 years in patients with high tumour burden follicular lymphoma responding to rituximab plus chemotherapy (PRIMA): a phase 3, randomized controlled trial. Lancet. 2011;377(9759):42-51.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228959
Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rituxan Hycela (rituximab and hyaluronidase human)
Follicular Lymphoma Indicated for the treatment of adult patients with: 1) Relapsed or refractory, follicular lymphoma as a single agent 2) Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy 3) Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions. **Diffuse Large B-cell Lymphoma** Indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions. **Chronic Lymphocytic Leukemia (CLL)** Indicated for the treatment of adult patients with

previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC). Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

2 . Criteria

Product Name:Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Diagnosis of follicular lymphoma

AND

2 - One of the following:

2.1 Disease is relapsed or refractory

OR

2.2 Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy

OR

2.3 Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

OR

2.4 Both of the following:

2.4.1 Disease is previously untreated

AND

2.4.2 Medication is used in combination with first-line chemotherapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

Product Name:Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Diffuse Large B-cell Lymphoma
Approval Length	12 months [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Diagnosis of diffuse large B-cell lymphoma

AND

2 - Disease is previously untreated

AND

3 - Medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy

AND

4 - One of the following:

4.1 Trial and failure, or intolerance to Ruxience

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

Product Name:Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 months [B]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia

AND

2 - Medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

3 . Endnotes

Treatment for DLBCL consists of up to 8 cycles of 21 days each, a total duration of 6 months [1,3]. There is little evidence that use of rituximab as continuation therapy following R-CHOP induction provides additional benefit above induction alone. [2] This is in contrast with follicular lymphoma, where evidence does support maintenance [4] therapy and NCCN recommends consolidation with rituximab monotherapy [3]. However, to account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.

Treatment for CLL consists of up to 6 cycles of 28 days each, a total duration of 6 months [1]. To account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.

An FDA-approved biosimilar is an appropriate substitute for rituximab. [3]

The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [4]

4 . References

Rixtuan Hycela Prescribing Information. Genentech, Inc. South San Francisco, CA. June 2021.

Habermann TM, Weller EA, Morrison VA, et al. Rituximab-CHOP versus CHOP alone or with maintenance rituximab in older patients with diffuse large B-cell lymphoma. J Clin Oncol. 2006;24(19):3121-3127.

The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 25, 2024.

Salles G, Seymour JF, Lopez-Guillermo A, et al. Rituximab maintenance for 2 years in patients with high tumour burden follicular lymphoma responding to rituximab plus chemotherapy (PRIMA): a phase 3, randomized controlled trial. Lancet. 2011;377(9759):42-51.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228618
Guideline Name	Rituximab - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rituxan (rituximab)
Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens. **Pediatric Non-Hodgkin's Lymphoma (NHL)** Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older. **Chronic Lymphocytic Leukemia (CLL)** Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination fludarabine

and cyclophosphamide (FC). Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.

Rheumatoid Arthritis (RA) In combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. Limitation of Use: Rituxan is not recommended for use in patients with severe, active infections.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids. Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.

Pemphigus Vulgaris Indicated for the treatment of moderate to severe Pemphigus Vulgaris (PV) in adult patients.

Off Label Uses: Immune Thrombocytopenic Purpura (ITP) Has been used for the treatment of immune or idiopathic thrombocytopenic purpura. [1, 2] Overall response rates of 35% to 52% in patients with refractory idiopathic thrombocytopenic purpura. [3, 4]

Waldenstrom's Macroglobulinemia Has been used for the treatment of relapsed/refractory Waldenstrom's macroglobulinemia. Rituximab monotherapy (1 to 8 cycles) has shown efficacy in limited studies. [5-8]

Drug Name: Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).

Rheumatoid Arthritis (RA) In combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adults with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids.

Off Label Uses: **Pediatric Non-Hodgkin's Lymphoma (NHL)** Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older. [25, C, D]

Drug Name: Riabni (rituximab-arrx)

Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).

Rheumatoid Arthritis (RA) Indicated in combination with methotrexate for the treatment of adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adults with Granulomatosis with Polyangiitis (GPA) (Wegener’s Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids.

Off Label Uses: **Pediatric Non-Hodgkin's Lymphoma (NHL)** Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older. [25, C, D]

2 . Criteria

Product Name:Rituxan, Truxima, Riabni	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN	RITUXIMAB IV SOLN 100 MG/10ML	21351860002020	Brand
RITUXAN	RITUXIMAB IV SOLN 500 MG/50ML	21351860002040	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 100 MG/10ML (10 MG/ML)	21351860102020	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 500 MG/50ML (10 MG/ML)	21351860102040	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 100 MG/10ML (10 MG/ML)	21351860142020	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 500 MG/50ML (10 MG/ML)	21351860142040	Brand

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:

methotrexate

leflunomide

sulfasalazine

AND

3 - Used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

Cimzia (certolizumab)

Enbrel (etanercept)

One formulary adalimumab product

Simponi (golimumab)

Rinvoq (upadacitinib)

Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

Actemra (tocilizumab)

Orencia (abatacept)

OR

4.2 Continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

AND

5 - Trial and failure or intolerance to Ruxience

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor. ** For review process only: Refer to the table in the Background sectio n for carrier-specific formulary adalimumab products

Product Name:Ruxience	
Diagnosis	Rheumatoid Arthritis (RA)

Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RUXIENCE	RITUXIMAB-PVVR IV SOLN 100 MG/10ML (10 MG/ML)	21351860602020	Brand
RUXIENCE	RITUXIMAB-PVVR IV SOLN 500 MG/50ML (10 MG/ML)	21351860602040	Brand

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:

methotrexate

leflunomide

sulfasalazine

AND

3 - Used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

Cimzia (certolizumab)

Enbrel (etanercept)

One formulary adalimumab product

Simponi (golimumab)

Rinvoq (upadacitinib)

Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

OR

4.2 Continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. ** For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products

Product Name:Rituxan, Ruxience, Truxima, Riabni	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN	RITUXIMAB IV SOLN 100 MG/10ML	21351860002020	Brand
RITUXAN	RITUXIMAB IV SOLN 500 MG/50ML	21351860002040	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 100 MG/10ML (10 MG/ML)	21351860102020	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 500 MG/50ML (10 MG/ML)	21351860102040	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 100 MG/10ML (10 MG/ML)	21351860142020	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 500 MG/50ML (10 MG/ML)	21351860142040	Brand
RUXIENCE	RITUXIMAB-PVVR IV SOLN 100 MG/10ML (10 MG/ML)	21351860602020	Brand
RUXIENCE	RITUXIMAB-PVVR IV SOLN 500 MG/50ML (10 MG/ML)	21351860602040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [10, 26, 27]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - At least 16 weeks have elapsed since last course of therapy [B]

Product Name:Riabni, Truxima	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TRUXIMA	RITUXIMAB-ABBS IV SOLN 100 MG/10ML (10 MG/ML)	21351860102020	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 500 MG/50ML (10 MG/ML)	21351860102040	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 100 MG/10ML (10 MG/ML)	21351860142020	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 500 MG/50ML (10 MG/ML)	21351860142040	Brand

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:

methotrexate

leflunomide

sulfasalazine

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming that medication is used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

Cimzia (certolizumab)

Enbrel (etanercept)

One formulary adalimumab product

Simponi (golimumab)

Rinvoq (upadacitinib)

Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

Actemra (tocilizumab)

Orencia (abatacept)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [10, 26, 27]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Ruxience

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. ** For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products

Product Name:Ruxience	
Diagnosis	Non-Hodgkin's Lymphoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RUXIENCE	RITUXIMAB-PVVR IV SOLN 100 MG/10ML (10 MG/ML)	21351860602020	Brand
RUXIENCE	RITUXIMAB-PVVR IV SOLN 500 MG/50ML (10 MG/ML)	21351860602040	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma

Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens

OR

1.2 Both of the following:

Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma

Used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma

Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy

Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.

OR

1.6 All of the following (off-label) [25, C, D]

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

CD-20-positive diffuse large B-cell lymphoma (DLBCL)

Burkitt lymphoma (BL)

Burkitt-like lymphoma (BLL)

Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

Product Name:Riabni, Rituxan, Truxima	
Diagnosis	Non-Hodgkin's Lymphoma

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN	RITUXIMAB IV SOLN 100 MG/10ML	21351860002020	Brand
RITUXAN	RITUXIMAB IV SOLN 500 MG/50ML	21351860002040	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 100 MG/10ML (10 MG/ML)	21351860102020	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 500 MG/50ML (10 MG/ML)	21351860102040	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 100 MG/10ML (10 MG/ML)	21351860142020	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 500 MG/50ML (10 MG/ML)	21351860142040	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma

Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens

OR

1.2 Both of the following:

Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma

Used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma

Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy

Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin’s lymphoma.

OR

1.6 All of the following (off-label for Riabni, Truxima) [25, C, D]:

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

CD-20-positive diffuse large B-cell lymphoma (DLBCL)

Burkitt lymphoma (BL)

Burkitt-like lymphoma (BLL)

Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Riabni, Truxima	
Diagnosis	Non-Hodgkin's Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TRUXIMA	RITUXIMAB-ABBS IV SOLN 100 MG/10ML (10 MG/ML)	21351860102020	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 500 MG/50ML (10 MG/ML)	21351860102040	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 100 MG/10ML (10 MG/ML)	21351860142020	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 500 MG/50ML (10 MG/ML)	21351860142040	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma

Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens

OR

1.2 Both of the following:

Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma

Used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma

Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy

Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.

OR

1.6 All of the following (off-label) [25, C, D]:

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

CD-20-positive diffuse large B-cell lymphoma (DLBCL)

Burkitt lymphoma (BL)

Burkitt-like lymphoma (BLL)

Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Ruxience

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

Product Name:Ruxience	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RUXIENCE	RITUXIMAB-PVVR IV SOLN 100 MG/10ML (10 MG/ML)	21351860602020	Brand
RUXIENCE	RITUXIMAB-PVVR IV SOLN 500 MG/50ML (10 MG/ML)	21351860602040	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Used in combination with fludarabine and cyclophosphamide

Product Name:Riabni, Rituxan, Truxima	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

RITUXAN	RITUXIMAB IV SOLN 100 MG/10ML	21351860002020	Brand
RITUXAN	RITUXIMAB IV SOLN 500 MG/50ML	21351860002040	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 100 MG/10ML (10 MG/ML)	21351860102020	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 500 MG/50ML (10 MG/ML)	21351860102040	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 100 MG/10ML (10 MG/ML)	21351860142020	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 500 MG/50ML (10 MG/ML)	21351860142040	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Used in combination with fludarabine and cyclophosphamide

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Riabni, Truxima	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TRUXIMA	RITUXIMAB-ABBS IV SOLN 100 MG/10ML (10 MG/ML)	21351860102020	Brand

TRUXIMA	RITUXIMAB-ABBS IV SOLN 500 MG/50ML (10 MG/ML)	21351860102040	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 100 MG/10ML (10 MG/ML)	21351860142020	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 500 MG/50ML (10 MG/ML)	21351860142040	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Used in combination with fludarabine and cyclophosphamide

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Ruxience

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

Product Name:Rituxan	
Diagnosis	Immune or Idiopathic Thrombocytopenic Purpura [1, 2] (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN	RITUXIMAB IV SOLN 100 MG/10ML	21351860002020	Brand
RITUXAN	RITUXIMAB IV SOLN 500 MG/50ML	21351860002040	Brand

Approval Criteria

1 - Diagnosis of immune or idiopathic thrombocytopenic purpura (off-label) [3, 4, 11]

AND

2 - Trial and failure, contraindication, or intolerance to at least ONE of the following: [12]

Glucocorticoids (e.g., prednisone, methylprednisolone)

Immunoglobulins (e.g., IVIg)

Splenectomy

AND

3 - Documented platelet count of less than 50 x 10^9 / L [11]

Product Name:Rituxan	
Diagnosis	Pemphigus Vulgaris
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN	RITUXIMAB IV SOLN 100 MG/10ML	21351860002020	Brand
RITUXAN	RITUXIMAB IV SOLN 500 MG/50ML	21351860002040	Brand

Approval Criteria

1 - Diagnosis of moderate to severe Pemphigus Vulgaris

Product Name:Rituxan	
Diagnosis	Pemphigus Vulgaris
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN	RITUXIMAB IV SOLN 100 MG/10ML	21351860002020	Brand
RITUXAN	RITUXIMAB IV SOLN 500 MG/50ML	21351860002040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Rituxan	
Diagnosis	Waldenstrom's macroglobulinemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN	RITUXIMAB IV SOLN 100 MG/10ML	21351860002020	Brand
RITUXAN	RITUXIMAB IV SOLN 500 MG/50ML	21351860002040	Brand

Approval Criteria

1 - Diagnosis of relapsed/refractory Waldenstrom's macroglobulinemia (off-label) [1, 2, 5-8]

Product Name:Ruxience	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RUXIENCE	RITUXIMAB-PVVR IV SOLN 100 MG/10ML (10 MG/ML)	21351860602020	Brand
RUXIENCE	RITUXIMAB-PVVR IV SOLN 500 MG/50ML (10 MG/ML)	21351860602040	Brand

Approval Criteria

1 - One of the following diagnoses:

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)

Microscopic Polyangiitis

AND

2 - Used in combination with glucocorticoids (e.g., prednisone)

Product Name:Riabni, Rituxan, Truxima	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN	RITUXIMAB IV SOLN 100 MG/10ML	21351860002020	Brand
RITUXAN	RITUXIMAB IV SOLN 500 MG/50ML	21351860002040	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 100 MG/10ML (10 MG/ML)	21351860102020	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 500 MG/50ML (10 MG/ML)	21351860102040	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 100 MG/10ML (10 MG/ML)	21351860142020	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 500 MG/50ML (10 MG/ML)	21351860142040	Brand

Approval Criteria

1 - One of the following diagnoses:

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)

Microscopic Polyangiitis

AND

2 - Used in combination with glucocorticoids (e.g., prednisone)

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Riabni, Truxima	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TRUXIMA	RITUXIMAB-ABBS IV SOLN 100 MG/10ML (10 MG/ML)	21351860102020	Brand
TRUXIMA	RITUXIMAB-ABBS IV SOLN 500 MG/50ML (10 MG/ML)	21351860102040	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 100 MG/10ML (10 MG/ML)	21351860142020	Brand
RIABNI	RITUXIMAB-ARRX IV SOLN 500 MG/50ML (10 MG/ML)	21351860142040	Brand

Approval Criteria

1 - One of the following diagnoses:

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)

Microscopic Polyangiitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is used in combination with glucocorticoids (e.g., prednisone)

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Ruxience

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products Adalimumab-adaz Hyrimoz Hadlima Adalimumab-fkjp

4 . Endnotes

Aggressive, continuous and early treatment with DMARDs may slow the destructive processes in RA by preventing or delaying cartilage and bone destruction. [11] Often used in combination, the most commonly prescribed DMARDs include hydroxychloroquine, sulfasalazine, leflunomide and methotrexate, with methotrexate being the gold standard.

An open-label extension analysis of RA patients previously treated with Rituxan was conducted. Patients were eligible for the second course if they demonstrated a greater than or equal to 20% reduction in both swollen joint count and the tender joint count at any visit 16 weeks after initial treatment or later and had active disease (swollen joint count greater than or equal to 8 and tender joint count greater than or equal to 8). Repeat courses of treatment were administered at the investigator’s discretion, with a minimum interval between treatment courses of 16 weeks. [15]

The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [22]

An FDA-approved biosimilar is an appropriate substitute for rituximab. [23, 25]

5 . References

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6 . Revision History

Date	Notes
11/7/2024	New program

Prior Authorization Guideline

Guideline ID	GL-228521
Guideline Name	Rivfloza (nedosiran)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rivfloza (nedosiran)
Primary Hyperoxaluria Type 1 (PH1) Indicated to lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m2.

2 . Criteria

Product Name:Rivfloza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RIVFLOZA	NEDOSIRAN SODIUM SUBCUTANEOUS SOLN PREF SYR 128 MG/0.8ML	5662605060E520	Brand
RIVFLOZA	NEDOSIRAN SODIUM SUBCUTANEOUS SOLN PREF SYR 160 MG/ML	5662605060E530	Brand
RIVFLOZA	NEDOSIRAN SODIUM SUBCUTANEOUS SOLN 80 MG/0.5ML	56626050602020	Brand

Approval Criteria

1 - Diagnosis of primary hyperoxaluria type 1 (PH1)

AND

2 - Disease has been confirmed by both of the following: [2]

2.1 One of the following:

Elevated urinary oxalate excretion

Elevated plasma oxalate concentration

Spot urinary oxalate to creatinine molar ratio greater than normal for age

AND

2.2 One of the following:

Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene

Liver biopsy demonstrating absence or reduced alanine:glyoxylate aminotransferase (AGT) activity

AND

3 - Patient is 9 years of age or older [A, 1]

AND

4 - Patient has preserved kidney function (e.g., eGFR greater than or equal to 30mL/min/1.73m^2)

AND

5 - Patient has not received a liver transplant [B, 2]

AND

6 - Prescribed by or in consultation with one of the following:

Hepatologist

Nephrologist

Urologist

Geneticist

Specialist with expertise in the treatment of PH1

Product Name:Rivfloza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RIVFLOZA	NEDOSIRAN SODIUM SUBCUTANEOUS SOLN PREF SYR 128 MG/0.8ML	5662605060E520	Brand
RIVFLOZA	NEDOSIRAN SODIUM SUBCUTANEOUS SOLN PREF SYR 160 MG/ML	5662605060E530	Brand
RIVFLOZA	NEDOSIRAN SODIUM SUBCUTANEOUS SOLN 80 MG/0.5ML	56626050602020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration)

AND

2 - Patient has not received a liver transplant

AND

3 - Prescribed by or in consultation with one of the following:

Hepatologist

Nephrologist

Urologist

Geneticist

Specialist with expertise in the treatment of PH1

3 . Endnotes

The safety and effectiveness of Rivfloza in patients younger than 9 years of age have not been established. [1]

Liver transplantation provides the definitive cure for PH type 1 by restoring the missing enzyme, which lowers oxalate production to the normal range. [2]

4 . References

Rivfloza prescribing information. Pyramid Laboratories. Costa Mesa, CA. September 2023.

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Prior Authorization Guideline

Guideline ID	GL-228963
Guideline Name	Roszet (rosuvastatin/ezetimibe) - ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Roszet (rosuvastatin/ezetimibe)
Non-familial hyperlipidemia Indicated as an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C). **Homozygous familial hypercholesterolemia (HoFH)** Indicated alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

2 . Criteria

Product Name:Roszet, Brand Ezetimibe-Rosuvastatin (ST)	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Brand
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 day supply) or intolerance to one of the following generics:

rosuvastatin

atorvastatin 40 mg

atorvastatin 80 mg

Product Name:Roszet, Brand Ezetimibe-Rosuvastatin (NF)	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Brand
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following diagnoses:

Non-familial hyperlipidemia

Homozygous familial hypercholesterolemia (HoFH)

AND

2 - Submission of medical records (e.g., chart notes) documenting history of a trial and failure (of a minimum 30 day supply) or intolerance to two of the following:

rosuvastatin

atorvastatin

simvastatin

AND

3 - Submission of medical records (e.g., chart notes) documenting history of trial and failure (of a minimum 30 day supply) or intolerance to ezetimibe

AND

4 - Physician has provided rationale for needing to use fixed-dose combination therapy with Roszet instead of taking individual products in combination

Product Name:Roszet, Brand Ezetimibe-Rosuvastatin (NF)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Brand
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic

EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy

3 . References

Roszet Prescribing Information. Althera Pharmaceuticals LLC. Morristown, NJ. June 2021.

Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.

Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014;35:2146-57.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228965
Guideline Name	Rozlytrek (entrectinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rozlytrek (entrectinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC), as detected by an FDA-approved test. **Solid Tumors** Indicated for the treatment of adult and pediatric patients older than 1 month of age with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion as detected by an FDA-approved test without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

2 . Criteria

Product Name:Rozlytrek	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ROZLYTREK	ENTRECTINIB CAP 100 MG	21533820000120	Brand
ROZLYTREK	ENTRECTINIB CAP 200 MG	21533820000130	Brand
ROZLYTREK	ENTRECTINIB PELLET PACK 50 MG	21533820003020	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Presence of ROS1 rearrangement as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Rozlytrek	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ROZLYTREK	ENTRECTINIB CAP 100 MG	21533820000120	Brand
ROZLYTREK	ENTRECTINIB CAP 200 MG	21533820000130	Brand
ROZLYTREK	ENTRECTINIB PELLET PACK 50 MG	21533820003020	Brand

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Presence of neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.) as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [A]

AND

3 - No known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions) [2]

AND

4 - Disease is one of the following:

Metastatic

Unresectable (including cases where surgical resection is likely to result in severe morbidity)

AND

5 - One of the following:

Disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) [3]

Disease has no satisfactory alternative treatments

Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ROZLYTREK	ENTRECTINIB CAP 100 MG	21533820000120	Brand
ROZLYTREK	ENTRECTINIB CAP 200 MG	21533820000130	Brand
ROZLYTREK	ENTRECTINIB PELLET PACK 50 MG	21533820003020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

The most common cancers listed in the pivotal trials which evaluated the efficacy of Rozlytrek were: sarcoma, lung, salivary gland tumors, breast, thyroid and colorectal cancer. [1]

4 . References

Rozlytrek Prescribing Information. Genentech USA, Inc. South San Francisco, CA. January 2024

Drilon A, Nagasubramanian R, Blake JF, et al. A next-generation TRK kinase inhibitor overcomes acquired resistance to prior TRK kinase inhibition in patients with TRK fusion-positive solid tumors. Cancer Discov. 2017 Sep;7(9):963-972.

5 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228524
Guideline Name	Rubraca (rucaparib) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rubraca (rucaparib)
Maintenance Treatment of BRCA-mutated Recurrent Ovarian cancer Indicated for the maintenance treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. **Metastatic Castration-Resistant Prostate Cancer with BRCA Mutations** Indicated for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

2 . Criteria

Product Name:Rubraca

Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RUBRACA	RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT)	21535570200320	Brand
RUBRACA	RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)	21535570200330	Brand
RUBRACA	RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT)	21535570200325	Brand

Approval Criteria

1 - Diagnosis of one of the following:

Epithelial ovarian cancer

Fallopian tube cancer

Primary peritoneal cancer

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to one of the following:

Lynparza

Zejula

OR

2.2 For continuation of prior therapy

Product Name:Rubraca

Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RUBRACA	RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT)	21535570200320	Brand
RUBRACA	RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)	21535570200330	Brand
RUBRACA	RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT)	21535570200325	Brand

Approval Criteria

1 - Diagnosis of castration-resistant prostate cancer (CRPC)

AND

2 - One of the following:

Trial and failure, contraindication, or intolerance to Lynparza

For continuation of prior therapy

Product Name:Rubraca	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RUBRACA	RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT)	21535570200320	Brand
RUBRACA	RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)	21535570200330	Brand

RUBRACA	RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT)	21535570200325	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Rubraca	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
RUBRACA	RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT)	21535570200320	Brand
RUBRACA	RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)	21535570200330	Brand
RUBRACA	RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT)	21535570200325	Brand

Approval Criteria

1 - Diagnosis of one of the following:

Epithelial ovarian cancer

Fallopian tube cancer

Primary peritoneal cancer

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to BOTH of the following:

Lynparza

Zejula

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Rubraca	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
RUBRACA	RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT)	21535570200320	Brand
RUBRACA	RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)	21535570200330	Brand
RUBRACA	RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT)	21535570200325	Brand

Approval Criteria

1 - Diagnosis of castration-resistant prostate cancer (CRPC)

AND

2 - One of the following:

Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Lynparza

Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

Rubraca Prescribing Information. Clovis Oncology, Inc. Boulder, CO. December 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Ovarian Cancer - v.1.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed July 1, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.2.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 1, 2024.

Prior Authorization Guideline

Guideline ID	GL-233274
Guideline Name	Rybrevant (amivantamab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	7/21/2021
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Rybrevant (amivantamab)
First-Line Treatment of NSCLC with EGFR Exon 20 Insertion Mutations Indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test. 2) Indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test. **First-Line Treatment of NSCLC with EGFR Exon 19 Deletions or Exon 21 L858R Substitution Mutations** Indicated in combination with lazertinib for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.

Previously Treated NSCLC with EGFRExon 19 Deletions or Exon 21 L858R Substitution Mutations Indicated in combination with carboplatin and pemetrexed, is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor

Previously Treated non-small Cell Lung Cancer (NSCLC) with EGFR Exon 20 Insertion Mutations Indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

2 . Criteria

Product Name:Rybrevant	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYBREVANT	AMIVANTAMAB-VMJW IV SOLN 350 MG/7ML	21359710802020	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

Locally advanced

Metastatic

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Presence of epidermal growth factor receptor (EGFR) exon 20 insertion mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3.1.2 One of the following:

3.1.2.1 Disease has progressed on or after platinum-based chemotherapy (e.g., carboplatin, cisplatin)

OR

3.1.2.2 Both of the following:

Used as first-line treatment of NSCLC

Used in combination with carboplatin and pemetrexed

OR

3.2 Both of the following:

3.2.1 Presence of epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test

AND

3.2.2 One of the following:

3.2.2.1 Both of the following:

Used as first line treatment of NSCLC

Used in combination with Lazcluze (lazertinib)

OR

3.2.2.2 Both of the following:

Disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor (e.g., osimertinib)

Used in combination with carboplatin and pemetrexed

AND

3.2.3 Used in combination with Lazcluze (lazertinib)

Product Name:Rybrevant	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYBREVANT	AMIVANTAMAB-VMJW IV SOLN 350 MG/7ML	21359710802020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Rybrevant Prescribing Information. Janssen Biotech, Inc. Horsham, PA. September 2024.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228964
Guideline Name	Rydapt (midostaurin)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rydapt (midostaurin) capsules
Acute Myeloid Leukemia Indicated for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Limitations of Use: Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML. **Aggressive Systemic Mastocytosis, Systemic Mastocytosis with Associated Hematological Neoplasm, or Mast Cell Leukemia** Indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

2 . Criteria

Product Name:Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 Month [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYDAPT	MIDOSTAURIN CAP 25 MG	21533030000130	Brand

Approval Criteria

1 - Diagnosis of newly diagnosed acute myeloid leukemia (AML)

AND

2 - FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [5]

AND

3 - Used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation

Product Name:Rydapt	
Diagnosis	Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), and Mast Cell Leukemia (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYDAPT	MIDOSTAURIN CAP 25 MG	21533030000130	Brand

Approval Criteria

1 - One of the following diagnoses: [4]

Aggressive systemic mastocytosis (ASM)

Systemic mastocytosis with associated hematological neoplasm (SM-AHN)

Mast cell leukemia (MCL)

Product Name:Rydapt	
Diagnosis	All Indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYDAPT	MIDOSTAURIN CAP 25 MG	21533030000130	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

Although Rydapt (midostaurin) is not FDA-approved for maintenance therapy, the pivotal trial was designed to include induction, re-induction (if indicated), post-remission (consolidation), and maintenance therapy for a total of 12 months. Therapy significantly improved event free survival and overall survival. [1-3]

4 . References

Rydapt Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. May 2023.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.1.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed February 27, 2023.

Stone RM, Mandrekar S, Sanford BL, et al. The multi-kinase inhibitor midostaurin (M) prolongs survival compared with placebo (P) in combination with daunorubicin (D)/cytarabine (C) induction (ind), high-dose c consolidation (consol), and as maintenance (maint) therapy in newly diagnosed acute myeloid leukemia (AML) patients (pts) age 18-60 with FLT3 Mutations (muts): an international prospective randomized (rand) p-controlled double-blind trial (CALGB 10603/RATIFY [Alliance]). Blood. 2015 Dec;126:6.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Systemic mastocytosis v.2.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf. Accessed February 27, 2023.

U.S. Food and Drug Administration: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools. Accessed December13, 2019.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228525
Guideline Name	Rystiggo (rozanolixizumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rystiggo (rozanolixizumab)
Generalized Myasthenia Gravis (gMG) Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

2 . Criteria

Product Name:Rystiggo	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYSTIGGO	ROZANOLIXIZUMAB-NOLI SUBCUTANEOUS SOLN 280 MG/2ML	99398270552020	Brand
RYSTIGGO	ROZANOLIXIZUMAB-NOLI SUBCUTANEOUS SOLN 420 MG/3ML	99398270552030	Brand
RYSTIGGO	ROZANOLIXIZUMAB-NOLI SUBCUTANEOUS SOLN 560 MG/4ML	99398270552040	Brand
RYSTIGGO	ROZANOLIXIZUMAB-NOLI SUBCUTANEOUS SOLN 840 MG/6ML	99398270552060	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

2.1.2 One of the following: [2]

2.1.2.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

2.1.2.2 Both of the following:

2.1.2.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

2.1.2.2.2 Trial and failure, contraindication, or intolerance to one of the following:

Chronic plasmapheresis or plasma exchange (PE)

Intravenous immunoglobulin (IVIG)

OR

2.2 Both of the following:

2.2.1 Patient is anti-muscle-specific tyrosine kinase (MuSK) antibody positive

AND

2.2.2 One of the following: [2]

2.2.2.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

2.2.2.2.2 Trial and failure, contraindication, or intolerance to one of the following:

Chronic plasmapheresis or plasma exchange (PE)

Intravenous immunoglobulin (IVIG)

Rituximab [3]

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Rystiggo	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYSTIGGO	ROZANOLIXIZUMAB-NOLI SUBCUTANEOUS SOLN 280 MG/2ML	99398270552020	Brand
RYSTIGGO	ROZANOLIXIZUMAB-NOLI SUBCUTANEOUS SOLN 420 MG/3ML	99398270552030	Brand
RYSTIGGO	ROZANOLIXIZUMAB-NOLI SUBCUTANEOUS SOLN 560 MG/4ML	99398270552040	Brand
RYSTIGGO	ROZANOLIXIZUMAB-NOLI SUBCUTANEOUS SOLN 840 MG/6ML	99398270552060	Brand

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

Rystiggo Prescribing Information. UCB, Inc., Smyrna, GA. June 2024.

Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.

Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current Treatment of Myasthenia Gravis. J Clin Med. 2022 Mar 14;11(6):1597.

Prior Authorization Guideline

Guideline ID	GL-233331
Guideline Name	Rytelo (imetelstat)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/18/2025
P&T Approval Date:	8/15/2024
P&T Revision Date:	

1 . Indications

Drug Name: Rytelo (imetelstat)
Anemia Associated with Myelodysplastic Syndrome (MDS) Indicated for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA).

2 . Criteria

Product Name:Rytelo

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYTELO	IMETELSTAT SODIUM FOR IV SOLN 47 MG	21535325602120	Brand
RYTELO	IMETELSTAT SODIUM FOR IV SOLN 188 MG	21535325602140	Brand

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Disease is low to intermediate-1 risk [A]

AND

3 - All of the following:

Hemoglobin less than 10 g/dL

Baseline absolute neutrophil count of 1.5 x 10^9 /L or greater

Baseline platelet count of 75 x 10^9 /L or greater

AND

4 - Both of the following:

Patient does not have a confirmed mutation with deletion 5q [del(5q)]

Patient has not received prior treatment with Revlimid (lenalidomide) or hypomethylating agents (e.g., azacitidine, decitabine)

AND

5 - Patient requires 4 or more red blood cell units over 8 weeks

AND

6 - One of the following:

Previous treatment with an erythropoiesis stimulating agent shows no response

Previous treatment with an erythropoiesis stimulating agent shows loss of response

Patient is ineligible for treatment with an erythropoiesis stimulating agent

Product Name:Rytelo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYTELO	IMETELSTAT SODIUM FOR IV SOLN 47 MG	21535325602120	Brand
RYTELO	IMETELSTAT SODIUM FOR IV SOLN 188 MG	21535325602140	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Definitions

Definition	Description

Myelodysplastic Syndromes (MDS)	Myelodysplastic syndromes (MDS) are an uncommon group of disorders characterized by abnormal blood-forming cells in the bone marrow, resulting in the reduction of peripheral blood cells, an elevated risk of acute myeloid leukemia (AML), and reduced survival. Anemia (low red blood cell counts), thrombocytopenia (low platelet counts), and leukopenia (low white blood cell counts) are common among patients with MDS [3]
The International Prognostic Scoring System (IPSS)	IPSS uses three "prognostic indicators" to predict the course of the patient's disease: • The percentage of leukemic blast cells in the marrow • The type of chromosomal changes, if any, in the marrow cells (cytogenetics) • The presence of one or more low blood cell counts (cytopenias) These 3 prognostic indicators are then assigned a total risk score from low, intermediate risk-1, intermediate risk -2, or high. [4]

4 . Endnotes

Disease was determined as low to intermediate-1 risk based on the The International Prognostic Scoring System (IPSS). [1,4]

5 . References

Rytelo Prescribing Information. Catalent Indiana, LLC. Bloomington, IN. June 2024.

ClinicalTrials.gov. Study to Evaluate Imetelstat (GRN163L) in Subjects With International Prognostic Scoring System (IPSS) Low or Intermediate-1 Risk Myelodysplastic Syndrome (MDS). Available at: https://www.clinicaltrials.gov/study/NCT02598661?cond=NCT02598661&rank=1. Accessed July 28, 2024.

ICER: Anemia in Myelodysplastic Syndrome. Available at: https://icer.org/assessment/myelodysplastic-syndrome-2024. Accessed July 28, 2024.

Leukemia and Lymphoma Society: The International Prognostic Scoring System. Available at: https://www.lls.org/myelodysplastic-syndromes/diagnosis/international-prognostic-scoring-system. Accessed July 28, 2024.

NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes v3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed July 29, 2024.

6 . Revision History

Date	Notes
2/18/2025	Quartz commercial copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-228527
Guideline Name	Sabril, Vigadrone, Vigafyde (vigabatrin)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sabril (vigabatrin), Vigadrone (vigabatrin)
Refractory Complex Partial Seizures Indicated as adjunctive therapy for adults and pediatric patients 2 years of age and older with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Sabril/Vigadrone is not indicated as a first line agent for complex partial seizures. **Infantile Spasms (1 Month to 2 Years of Age)** Indicated as monotherapy for pediatric patients with infantile spasms (IS) 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.
Drug Name: Vigafyde (vigabatrin)
Infantile Spasms (1 Month to 2 Years of Age) Indicated as monotherapy for pediatric patients with infantile spasms (IS) 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

2 . Criteria

Product Name:Generic vigabatrin, Vigadrone	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIGABATRIN	VIGABATRIN POWD PACK 500 MG	72170085003020	Generic
VIGADRONE	VIGABATRIN POWD PACK 500 MG	72170085003020	Generic
VIGABATRIN	VIGABATRIN TAB 500 MG	72170085000320	Generic

Approval Criteria

1 - Both of the following:

Diagnosis of infantile spasms [A]

Patient is 1 month to 2 years of age

OR

2 - All of the following:

2.1 Diagnosis of complex partial seizures

AND

2.2 Patient is 2 years of age or older

AND

2.3 Used as adjunctive therapy

AND

2.4 One of the following:

Trial and failure, contraindication, or intolerance to two formulary anticonvulsants [e.g., Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)] [B]

For continuation of prior therapy

Product Name:Brand Sabril	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SABRIL	VIGABATRIN TAB 500 MG	72170085000320	Brand
SABRIL	VIGABATRIN POWD PACK 500 MG	72170085003020	Brand

Approval Criteria

1 - All of the following:

1.1 Diagnosis of infantile spasms [A]

AND

1.2 Patient is 1 month to 2 years of age

AND

1.3 One of the following:

Trial and failure or intolerance to generic vigabatrin tablets or oral suspension

For continuation of prior therapy

OR

2 - All of the following: [A]

2.1 Diagnosis of complex partial seizures

AND

2.2 Patient is 2 years of age or older

AND

2.3 Used as adjunctive therapy

AND

2.4 One of the following:

2.4.1 Both of the following:

Trial and failure, contraindication, or intolerance to two formulary anticonvulsants [e.g., Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)] [B]

Trial and failure or intolerance to generic vigabatrin tablets or oral suspension

OR

2.4.2 For continuation of prior therapy

Product Name:Brand Vigafyde	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIGAFYDE	VIGABATRIN ORAL SOLN 100 MG/ML	72170085002020	Brand

Approval Criteria

1 - Both of the following:

Diagnosis of infantile spasms [A]

Patient is 1 month to 2 years of age

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to generic vigabatrin oral suspension

OR

2.2 For continuation of prior therapy

Product Name:Generic vigabatrin, Vigadrone, Brand Sabril, Brand Vigafyde	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SABRIL	VIGABATRIN TAB 500 MG	72170085000320	Brand
SABRIL	VIGABATRIN POWD PACK 500 MG	72170085003020	Brand
VIGABATRIN	VIGABATRIN POWD PACK 500 MG	72170085003020	Generic
VIGADRONE	VIGABATRIN POWD PACK 500 MG	72170085003020	Generic

VIGABATRIN	VIGABATRIN TAB 500 MG	72170085000320	Generic
VIGAFYDE	VIGABATRIN ORAL SOLN 100 MG/ML	72170085002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) program overview: Vigabatrin Sponsors have created Vigabatrin REMS program to administer the REMS process, which facilitates access to vigabatrin only through select specialty and inpatient pharmacies. The REMS includes the following elements: 1) Patient Guide: outlines the vision loss that can occur with vigabatrin treatment; 2) Elements to Assure Safe Use (ETASU): Vigabatrin Sponsors will maintain a database of certified prescribers (e.g., must counsel regarding the risks associated with vigabatrin, including vission loss; ensure periodic visual monitoring is performed on an ongoing basis, report any adverse event suggestive of vision loss; enrolling patients taking vigabatrin in the REMS program) and will ensure that prescribers comply with the requirements of the REMS and may de-certify noncompliant prescribers. [3] Assessing the effectiveness of vigabatrin should be done within 12 weeks for CPS patients and within 2-4 weeks for IS. Vision monitoring is mandatory in adults and it is required to the extent possible in infants at baseline (no later than 4 weeks after starting vigabatrin) and at least 3 months while on therapy. Vision testing is also required about 3-6 months after the discontinuation of vigabatrin therapy. [1, 2] Under REMS requirement, pharmacies that dispense vigabatrin will be specially certified. Vigabatrin Sponsors will ensure that each patient treated with vigabatrin is enrolled in the Vigabatrin REMS before vigabatrin is dispensed and that vigabatrin will be dispensed to patients with documentation of safe-use conditions. 3) Implementation system: Vigabatrin Sponsors will ensure that vigabatrin is only distributed to certified pharmacies by ensuring that the wholesale/distributors comply with the program requirements, which includes submission of distribution records of all vigabatrin shipments to the REMS program. Vigabatrin Sponsors will maintain a secure database of all certified pharmacies and patients enrolled in the REMS program. A REMS program call center and website will be maintained by Vigabatrin Sponsors in order to provide resources and support for all aspects of the REMS program. [3]

To improve patient care and facilitate clinical research, the International League Against Epilepsy (ILAE) appointed a Task Force to formulate a consensus definition of drug resistant epilepsy. The following definition was formulated: Drug resistant epilepsy may be defined as failure of adequate trials of two tolerated and appropriately chosen and used antiepileptic drug (AED) schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom. [4]

4 . References

Sabril Prescribing Information. Lundbeck. Deerfield, IL. May 2020.

Vigadrone Prescribing Information. Upsher-Smith Laboritories, LLC. Maple Grove, MN. February 2020.

REMS@FDA: Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) Program. U.S. Food and Drug Administration; Available at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=364. Accessed February 15, 2021.

Kwan P, Arzimanoglou A, Berg AT, et al. Definition of drug resistant epilepsy: consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. Epilepsia. 2010 Jun;51(6):1069-77.

Vigafyde Prescribing Information. Pyros Pharmaceuticals, Inc. Parsippany, NJ. June 2024.

Prior Authorization Guideline

Guideline ID	GL-229162
Guideline Name	Saphnelo (anifrolumab-fnia)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/20/2021
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Saphnelo (anifrolumab-fnia)
Systemic Lupus Erythematosus (SLE) Indicated for the treatment of adult patients with moderate to severe SLE, who are receiving standard therapy. Limitations of Use: The efficacy of Saphnelo has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of Saphnelo is not recommended in these situations.

2 . Criteria

Product Name:Saphnelo

Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAPHNELO	ANIFROLUMAB-FNIA IV SOLN 300 MG/2ML	99427010252020	Brand

Approval Criteria

1 - Diagnosis of moderate to severe systemic lupus erythematosus (SLE)

AND

2 - Trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [4]

AND

3 - Currently receiving standard of care treatment for SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [1-3]

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name:Saphnelo	
Approval Length	6 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

SAPHNELO	ANIFROLUMAB-FNIA IV SOLN 300 MG/2ML	99427010252020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decrease or stabilization of symptoms, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications)

3 . Endnotes

SLE is a disease that fluctuates. The undulating course of typical lupus patients requires frequent reassessment. A 6-month authorization period is reasonable. [2]

4 . References

Saphnelo Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. August 2024.

Per clinical consult with rheumatologist, October 4, 2017.

American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus. Arthritis Rheum. 1999 Sep;42(9):1785-96.

Fanouriakis A, Kostopoulou M, Alunno A, et al. Ann Rheum Dis 2019;78:736–745.

Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. Ann Rheum Dis. 2024 Jan 2;83(1):15-29.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-233257
Guideline Name	Sapropterin Products
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/25/2016
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Kuvan (sapropterin dihydrochloride)
Phenylketonuria Indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). It is to be used in conjunction with a Phe-restricted diet.
Drug Name: Javygtor (sapropterin dihydrochloride)
Phenylketonuria Indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). It is to be used in conjunction with a Phe-restricted diet.

2 . Criteria

Product Name:Brand Kuvan, Brand Javygtor	
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KUVAN	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 100 MG	30908565103020	Brand
KUVAN	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 500 MG	30908565103040	Brand
KUVAN	SAPROPTERIN DIHYDROCHLORIDE TAB 100 MG	30908565100320	Brand
JAVYGTOR	SAPROPTERIN DIHYDROCHLORIDE TAB 100 MG	30908565100320	Brand
JAVYGTOR	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 100 MG	30908565103020	Brand
JAVYGTOR	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 500 MG	30908565103040	Brand

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will have Phe blood levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response [E]

AND

4 - Trial and failure or intolerance to generic sapropterin

Product Name:Brand Kuvan, Brand Javygtor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KUVAN	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 100 MG	30908565103020	Brand
KUVAN	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 500 MG	30908565103040	Brand
KUVAN	SAPROPTERIN DIHYDROCHLORIDE TAB 100 MG	30908565100320	Brand
JAVYGTOR	SAPROPTERIN DIHYDROCHLORIDE TAB 100 MG	30908565100320	Brand
JAVYGTOR	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 100 MG	30908565103020	Brand
JAVYGTOR	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 500 MG	30908565103040	Brand

Approval Criteria

1 - Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline [B -D]

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will continue to have blood Phe levels measured periodically during therapy [E]

AND

4 - Trial and failure or intolerance to generic sapropterin

Product Name:Generic sapropterin	
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAPROPTERIN DIHYDROCHLORIDE	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 100 MG	30908565103020	Generic
SAPROPTERIN DIHYDROCHLORIDE	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 500 MG	30908565103040	Generic
SAPROPTERIN DIHYDROCHLORIDE	SAPROPTERIN DIHYDROCHLORIDE TAB 100 MG	30908565100320	Generic

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will have Phe blood levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response [E]

Product Name:Generic sapropterin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAPROPTERIN DIHYDROCHLORIDE	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 100 MG	30908565103020	Generic
SAPROPTERIN DIHYDROCHLORIDE	SAPROPTERIN DIHYDROCHLORIDE POWDER PACKET 500 MG	30908565103040	Generic

SAPROPTERIN DIHYDROCHLORIDE	SAPROPTERIN DIHYDROCHLORIDE TAB 100 MG	30908565100320	Generic

Approval Criteria

1 - Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline [B -D]

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will continue to have blood Phe levels measured periodically during therapy [E]

3 . Endnotes

All patients who are treating phenylketonuria (PKU) with sapropterin should also be treated with a phenylalanine (Phe) restricted diet [1].

Sapropterin was evaluated in a phase III, randomized, placebo-controlled trial to determine its efficacy in reducing blood Phe concentration [2]. The primary endpoint was mean change from baseline in concentration of Phe in blood after 6 weeks. The mean age was 20 years. Results showed that after 6 weeks of therapy, patients who received sapropterin (n=41) had a decrease in mean blood Phe of 236 micromol/L, compared with a 3 micromol/L increase in the placebo group (n=47; p less than 0.0001).

Patients should be evaluated for response to therapy after treatment with saproterin at 20mg/kg per day for a period of one month [1]. The 2 month initial authorization duration allows for patients who start on 10mg/kg per day for the first month, to increase their dose to 20mg/kg per day for an additional month prior to evaluation of response.

In clinical trials, response to therapy was defined as greater than or equal to 30% decrease in blood Phe from baseline [1]. The American College of Medical Genetics and Genomics guideline notes a significant decline in blood Phe is expected in sapropterin responders once treatment is started [3]. A reduction of 30% is most often cited in the literature as evidence of effective Phe reduction.

Phe blood levels should be checked after one week of sapropterin treatment and periodically after that to assess blood Phe control [1].

4 . References

Kuvan prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. August 2024.

Levy HL, Milanowski A, Chakrapani A, et al. Efficacy of sapropterin dihydrochloride (tetrahydrobiopterin, 6R-BH4) for reduction of phenylalanine concentration in patients with phenylketonuria: a phase III randomised placebo-controlled study. Lancet. 2007;370(9586):504-10.

Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014 Feb;16(2):188-200.

Javygtor prescribing information. Dr. Reddys Laboratories Inc. Princeton, NJ. May 2022.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Scemblix (asciminib)

Prior Authorization Guideline

Guideline ID	GL-228530
Guideline Name	Scemblix (asciminib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Scemblix
Philadelphia chromosome-positive chronic myeloid leukemia Indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs). Scemblix is also indicated for the treatment of Ph+CML in CP with the T315I mutation.

2 . Criteria

Product Name:Scemblix	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SCEMBLIX	ASCIMINIB HCL TAB 20 MG	21531806100320	Brand
SCEMBLIX	ASCIMINIB HCL TAB 40 MG	21531806100340	Brand
SCEMBLIX	ASCIMINIB HCL TAB 100 MG	21531806100380	Brand

Approval Criteria

1 - Diagnosis of chronic myelogenous/myeloid leukemia (CML) [1, 2]

AND

2 - Disease is Philadelphia chromosome-positive (Ph+)

AND

3 - Disease is in chronic phase

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Patient has been previously treated with two or more alternative tyrosine kinase inhibitors (TKI) [e.g., Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib), Iclusig (ponatinib)]

AND

4.1.2 Prescribed medication will be dosed at a maximum of 80 mg per day

OR

4.2 Both of the following:

4.2.1 Disease is T315I mutation positive

AND

4.2.2 Prescribed medication will be dosed at a maximum of 400 mg per day

Product Name:Scemblix	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SCEMBLIX	ASCIMINIB HCL TAB 20 MG	21531806100320	Brand
SCEMBLIX	ASCIMINIB HCL TAB 40 MG	21531806100340	Brand
SCEMBLIX	ASCIMINIB HCL TAB 100 MG	21531806100380	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Scemblix [prescribing information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation. November 2023.

Scemblix. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Accessed December 3, 2021. http://www.micromedexsolutions.com.

Scenesse (afamelanotide)

Prior Authorization Guideline

Guideline ID	GL-228531
Guideline Name	Scenesse (afamelanotide)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Scenesse (afamelanotide)
Erythropoietic protoporphyria - Phototoxic dermatitis Indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP).

2 . Criteria

Product Name:Scenesse	
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SCENESSE	AFAMELANOTIDE ACETATE IMPLANT 16 MG	90922010102320	Brand

Approval Criteria

1 - Diagnosis of erythropoietic protoporphyria (EPP) confirmed by laboratory or genetic testing [B]

AND

2 - Patient has history of phototoxic reactions

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Hepatologist

Product Name:Scenesse	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SCENESSE	AFAMELANOTIDE ACETATE IMPLANT 16 MG	90922010102320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increased duration of exposure to direct sunlight without pain, decreased number of phototoxic reactions)

3 . Endnotes

Patients enrolled in clinical trial (Study CUV039, NCT 01605136) were assessed after 180 days and consultant agreed that 6 month approval duration is appropriate to determine if patient is responding to therapy. [1, 2]

Per recommendation from consultant to avoid off-label use, diagnosis of erythropoietic protoporphyria (EPP) should be confirmed by laboratory (porphyrin levels in serum and stool) or genetic testing. [2]

4 . References

Scenesse Prescribing Information. Clinuvel, Inc. West Menlo Park, CA. January 2023.

Per clinical consult with dermatologist, December 19, 2019.

Selzentry (maraviroc)

Prior Authorization Guideline

Guideline ID	GL-229131
Guideline Name	Selzentry (maraviroc)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/12/2013
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Selzentry (maraviroc)
CCR5-tropic HIV-1 Indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 2 kg. Limitations of Use: SELZENTRY is not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1

2 . Criteria

Product Name:Brand Selzentry tablets, generic maraviroc 150mg and 300mg tablets, Selzentry solution

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SELZENTRY	MARAVIROC TAB 150 MG	12102060000320	Brand
SELZENTRY	MARAVIROC TAB 300 MG	12102060000330	Brand
SELZENTRY	MARAVIROC TAB 25 MG	12102060000305	Brand
SELZENTRY	MARAVIROC TAB 75 MG	12102060000310	Brand
SELZENTRY	MARAVIROC ORAL SOLN 20 MG/ML	12102060002020	Brand
MARAVIROC	MARAVIROC TAB 150 MG	12102060000320	Generic
MARAVIROC	MARAVIROC TAB 300 MG	12102060000330	Generic

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of CCR5-tropic HIV-1 infection as confirmed by a highly sensitive tropism assay

AND

1.1.2 Patient is currently taking or will be prescribed an optimized background antiretroviral therapy regimen

AND

1.1.3 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

3 . References

Selzentry Prescribing Information. ViiV Healthcare. Durham, NC. September 2022.

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. 2023. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed September 14, 2023.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228966
Guideline Name	Sensipar (cinacalcet)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sensipar (cinacalcet)
Secondary Hyperparathyroidism Indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis. Limitations of Use: Sensipar is not indicated for use in adult patients with CKD who are not on dialysis because of an increased risk of hypocalcemia. **Parathyroid Carcinoma** Indicated for the treatment of hypercalcemia in adult patients with parathyroid carcinoma. **Primary Hyperparathyroidism** Indicated for the treatment of hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

2 . Criteria

Product Name:Brand Sensipar, generic cinacalcet	
Diagnosis	Secondary hyperparathyroidism [1-3]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SENSIPAR	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Brand
SENSIPAR	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Brand
SENSIPAR	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Brand
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Generic

Approval Criteria

1 - Patient is 18 years of age or older [1, A]

AND

2 - Diagnosis of secondary hyperparathyroidism with chronic kidney disease on dialysis

AND

3 - Trial and failure, contraindication or intolerance to both of the following:

A phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.)

A vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.)

AND

4 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)

AND

5 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

Product Name:Brand Sensipar, generic cinacalcet	
Diagnosis	Hypercalcemia with parathyroid carcinoma
Approval Length	12 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SENSIPAR	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Brand
SENSIPAR	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Brand
SENSIPAR	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Brand
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Generic

Approval Criteria

1 - Patient is 18 years of age or older [1, A]

AND

2 - Diagnosis of hypercalcemia with parathyroid carcinoma

AND

3 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)

AND

4 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

Product Name:Brand Sensipar, generic cinacalcet	
Diagnosis	Severe hypercalcemia with primary hyperparathyroidism [4-5]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SENSIPAR	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Brand
SENSIPAR	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Brand
SENSIPAR	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Brand
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Generic

Approval Criteria

1 - Patient is 18 years of age or older [1, A]

AND

2 - Diagnosis of severe hypercalcemia (level greater than 1 mg/dL above the upper limit of normal) with primary hyperparathyroidism [C, D]

AND

3 - Patient is unable to undergo parathyroidectomy

AND

4 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)

AND

5 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

Product Name:Brand Sensipar, generic cinacalcet	
Diagnosis	All diagnoses listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SENSIPAR	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Brand
SENSIPAR	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Brand
SENSIPAR	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Brand
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

Sensipar is not indicated for use in pediatric patients. In aggregate, pediatric clinical studies did not establish a safe and effective Sensipar dosing regimen for the pediatric

population. Dosing with Sensipar in Pediatric Study 1 was stopped because of a fatality in a Sensipar-treated individual. The individual was noted to be severely hypocalcemic at the time of death. [1]

In the pivotal study of Sensipar for parathyroid carcinoma, patients were treated with maintenance therapy for up to 48 weeks. [1]

As recommended by an endocrinologist consultant, hypercalcemia is defined as serum calcium level greater than or equal to 12.5 mg/dL. [5]

In the pivotal study of Sensipar for primary hyperparathyroidism, severe hypercalcemia was defined as a screening serum calcium level of > 12.5 mg/dL. The median exposure to Sensipar was 270 days (range: 32-1,105 days). [1]

4 . References

Sensipar prescribing information. Amgen Inc. Thousand Oaks, CA. December 2019.

Block GA, Martin KJ, de Francisco AL, et al. Cinacalcet for secondary hyperparathyroidism in patients receiving hemodialysis. N Engl J Med. 2004;350(15):1516-25.

Lindberg JS, Culleton B, Wong G, et al. Cinacalcet HCl, an oral calcimimetic agent for the treatment of secondary hyperparathyroidism in hemodialysis and peritoneal dialysis: a randomized, double-blind, multicenter study. J Am Soc Nephrol. 2005;16(3):800-7.

Peacock M, Bilezikian JP, Klassen PS, et al. Cinacalcet hydrochloride maintains long-term normocalcemia in patients with primary hyperparathyroidism. J Clin Endocrinol Metab. 2005;90(1):135-41.

Per clinical consult with endocrinologist, July 5, 2011.

Cinacalcet Prescribing Information. Actavis Pharma, Inc. Parsippany, NJ. August 2018.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228534
Guideline Name	Sernivo (betamethasone dipropionate)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sernivo (betamethasone dipropionate)
Mild to moderate plaque psoriasis Indicated for the treatment of mild to moderate plaque psoriasis in patients 18 years of age or older.

2 . Criteria

Product Name:Sernivo	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic

SERNIVO	BETAMETHASONE DIPROPIONATE SPRAY EMULSION 0.05% (BASE EQUIV)	90550020001620	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure within the past 180 days, contraindication, or intolerance to three of the following:

Clocortolone 0.1% cream

Fluocinolone acetonide 0.025% ointment

Flurandrenolide 0.05% ointment

Fluticasone propionate 0.05% cream

Hydrocortisone valerate 0.2% ointment

Mometasone furoate 0.1% cream/lotion/solution

Triamcinolone 0.1% cream/ointment

Triamcinolone 0.05% ointment

Triamcinolone aerosol spray

Brand/generic Taclonex (calcipotriene-betamethasonne dipropionate) suspension

Enstilar foam

3 . References

Sernivo Prescribing Information. Encore Dermatology, Inc. Scottsdale, AZ. March 2020.

Prior Authorization Guideline

Guideline ID	GL-228536
Guideline Name	Sevenfact [coagulation factor VIIa (recombinant)-jncw] - ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sevenfact [coagulation factor VIIa (recombinant)-jncw]
Hemophilia A or B with Inhibitors Indicated for the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors. Limitation of Use: Sevenfact is not indicated for the treatment of patients with congenital Factor VII deficiency.

2 . Criteria

Product Name:Sevenfact	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
SEVENFACT	COAGULATION FACTOR VIIA (RECOM)-JNCW FOR INJ 1 MG (1000 MCG)	85100026402117	Brand
SEVENFACT	COAGULATION FACTOR VIIA (RECOM)-JNCW FOR INJ 5 MG (5000 MCG)	85100026402145	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial of or intolerance to Novoseven RT

Product Name:Sevenfact	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SEVENFACT	COAGULATION FACTOR VIIA (RECOM)-JNCW FOR INJ 1 MG (1000 MCG)	85100026402117	Brand
SEVENFACT	COAGULATION FACTOR VIIA (RECOM)-JNCW FOR INJ 5 MG (5000 MCG)	85100026402145	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial of or intolerance to Novoseven RT

3 . References

Sevenfact Prescribing Information. Hema Biologics, Louisville, KY. November 2022.

Prior Authorization Guideline

Guideline ID	GL-228971
Guideline Name	SGLT2 Inhibitors - ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Brenzavvy (bexagliflozin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Brenzavvy is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.
Drug Name: Invokamet (canagliflozin/metformin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Canagliflozin is indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.
Drug Name: Invokamet XR (canagliflozin/metformin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Canagliflozin is indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.

Drug Name: Invokana (canagliflozin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of use: Invokana is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. Not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m 2. INVOKANA is likely to be ineffective in this setting based upon its mechanism of action.

Drug Name: Qtern (dapagliflozin and saxagliptin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: QTERN is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus

Drug Name: Segluromet (ertugliflozin and metformin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.

Drug Name: Steglatro (ertugliflozin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus

Drug Name: Steglujan (ertugliflozin and sitagliptin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. Has not been studied in patients

with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using STEGLUJAN.
Drug Name: Inpefa
Heart failure or Type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors Indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with: 1) heart failure, or 2) type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

2 . Criteria

Product Name:Brand Bexagliflozin, Brenzavvy, Qtern, Segluromet, Steglatro, Steglujan, Invokamet, Invokamet XR, Invokana	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
INVOKANA	CANAGLIFLOZIN TAB 100 MG	27700020000320	Brand
INVOKANA	CANAGLIFLOZIN TAB 300 MG	27700020000330	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 50-500 MG	27996002200320	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 50-1000 MG	27996002200330	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 150-500 MG	27996002200340	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 150-1000 MG	27996002200350	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 50-500 MG	27996002207520	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 50-1000 MG	27996002207530	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 150-500 MG	27996002207540	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 150-1000 MG	27996002207550	Brand
QTERN	DAPAGLIFLOZIN-SAXAGLIPTIN TAB 10-5 MG	27996502200330	Brand
STEGLATRO	ERTUGLIFLOZIN L-PYROGLUTAMIC ACID TAB 5 MG (BASE EQUIV)	27700055200320	Brand

STEGLATRO	ERTUGLIFLOZIN L-PYROGLUTAMIC ACID TAB 15 MG (BASE EQUIV)	27700055200340	Brand
STEGLUJAN	ERTUGLIFLOZIN-SITAGLIPTIN TAB 5-100 MG	27996502350320	Brand
STEGLUJAN	ERTUGLIFLOZIN-SITAGLIPTIN TAB 15-100 MG	27996502350330	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 2.5-500 MG	27996002450310	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 2.5-1000 MG	27996002450320	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 7.5-500 MG	27996002450330	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 7.5-1000 MG	27996002450340	Brand
QTERN	DAPAGLIFLOZIN-SAXAGLIPTIN TAB 5-5 MG	27996502200320	Brand
BRENZAVVY	BEXAGLIFLOZIN TAB 20 MG	27700010000320	Brand
BEXAGLIFLOZIN	BEXAGLIFLOZIN TAB 20 MG	27700010000320	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

metformin

metformin ER

glipizide-metformin

glyburide-metformin

pioglitazone-metformin

OR

2.2 Patient has one of the following (Applies to Invokamet, Invokamet XR, and Invokana only):

History of atherosclerotic cardiovascular disease (ASCVD)

High risk for ASCVD with multiple risk factors (e.g., obesity, hypertension, smoking, dyslipidemia, albuminuria)

Established chronic kidney disease (CKD)

Heart failure

AND

3 - Trial and failure of a minimum 90 day supply, or intolerance to any one of the following preferred brands:

Farxiga

Xigduo XR

AND

4 - Trial and failure of a minimum 90 day supply, or intolerance to one of the following:

Glyxambi

Jardiance

Synjardy

Synjardy XR

Trijardy XR

Product Name:Inpefa	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
INPEFA	SOTAGLIFLOZIN TAB 200 MG	40750010000320	Brand
INPEFA	SOTAGLIFLOZIN TAB 400 MG	40750010000340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 90 day supply, contraindication, or intolerance to both of the following:

Farxiga

Jardiance

Product Name:Brand Bexagliflozin, Brenzavvy, Qtern, Segluromet, Steglatro, Steglujan, Invokamet, Invokamet XR, Invokana	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
INVOKANA	CANAGLIFLOZIN TAB 100 MG	27700020000320	Brand
INVOKANA	CANAGLIFLOZIN TAB 300 MG	27700020000330	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 50-500 MG	27996002200320	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 50-1000 MG	27996002200330	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 150-500 MG	27996002200340	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 150-1000 MG	27996002200350	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 50-500 MG	27996002207520	Brand

INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 50-1000 MG	27996002207530	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 150-500 MG	27996002207540	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 150-1000 MG	27996002207550	Brand
QTERN	DAPAGLIFLOZIN-SAXAGLIPTIN TAB 10-5 MG	27996502200330	Brand
STEGLATRO	ERTUGLIFLOZIN L-PYROGLUTAMIC ACID TAB 5 MG (BASE EQUIV)	27700055200320	Brand
STEGLATRO	ERTUGLIFLOZIN L-PYROGLUTAMIC ACID TAB 15 MG (BASE EQUIV)	27700055200340	Brand
STEGLUJAN	ERTUGLIFLOZIN-SITAGLIPTIN TAB 5-100 MG	27996502350320	Brand
STEGLUJAN	ERTUGLIFLOZIN-SITAGLIPTIN TAB 15-100 MG	27996502350330	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 2.5-500 MG	27996002450310	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 2.5-1000 MG	27996002450320	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 7.5-500 MG	27996002450330	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 7.5-1000 MG	27996002450340	Brand
QTERN	DAPAGLIFLOZIN-SAXAGLIPTIN TAB 5-5 MG	27996502200320	Brand
BRENZAVVY	BEXAGLIFLOZIN TAB 20 MG	27700010000320	Brand
BEXAGLIFLOZIN	BEXAGLIFLOZIN TAB 20 MG	27700010000320	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Submission of medical records (e.g., chart notes) or paid claims confirming one of the following:

2.1 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

metformin

metformin ER

glipizide-metformin

glyburide-metformin

pioglitazone-metformin

OR

2.2 Patient has one of the following (Applies to Invokamet, Invokamet XR, and Invokana only):

History of atherosclerotic cardiovascular disease (ASCVD)

High risk for ASCVD with multiple risk factors (e.g., obesity, hypertension, smoking, dyslipidemia, albuminuria)

Established chronic kidney disease (CKD)

Heart failure

AND

3 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure of a minimum 90 day supply, or intolerance to any one of the following preferred brands:

Farxiga

Xigduo XR

AND

4 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure of a minimum 90 day supply, or intolerance to one of the following:

Glyxambi

Jardiance

Synjardy

Synjardy XR

Trijardy XR

Product Name:Inpefa	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
INPEFA	SOTAGLIFLOZIN TAB 200 MG	40750010000320	Brand
INPEFA	SOTAGLIFLOZIN TAB 400 MG	40750010000340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Submission of medical records (e.g., chart notes) or piad claims confirming trial and failure of a minimum 90 day supply, contraindication, or intolerance to both of the following:

Farxiga

Jardiance

3 . References

Invokana Prescribing Information. Janssen. Titusville, NJ. July 2023.

Invokamet Prescribing Information. Janssen. Titusville, NJ. January 2024.

Invokamet XR Prescribing information. Janssen Ortho, LLC. Titusville, NJ. January 2024.

Qtern Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. September 2023.

Segluromet Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. June 2024.

Steglatro Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. June 2024.

Steglujan Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. June 2024.

Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017;136:e137–e161.

Maddox TM, Januzzi JL, Allen LA, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction. J Am Coll Cardiol. 2021;77 (6): 772–810.

Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. Journal of Cardiac Failure. Published online April 2022.

Brenzavvy Prescribing Information. TheracosBio, LLC. Marlborough, MA. February 2024.

Inpefa Prescribing Information. Lexicon Pharmaceuticals, Inc. The Woodlands, TX. January 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228537
Guideline Name	Short Acting Insulin - ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Humalog (insulin lispro)
Diabetes Mellitus Indicated to improve glycemic control in adults and children with diabetes mellitus.
Drug Name: Lyumjev (insulin lispro-aabc)
Diabetes Mellitus Indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.
Drug Name: Novolog (insulin aspart)
Diabetes Mellitus Indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.
Drug Name: Novolin (human insulin)
Diabetes Mellitus Indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.

2 . Criteria

Product Name:Humalog Tempo Pen, Lyumjev Tempo Pen	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
LYUMJEV TEMPO PEN	INSULIN LISPRO-AABC SOLN PEN-INJ W/TRANSMIT PORT 100 UNIT/ML	2710400505D224	Brand
HUMALOG TEMPO PEN	INSULIN LISPRO SOLN PEN-INJ W/TRANSMITTER PORT 100 UNIT/ML	2710400500D224	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:

Brand Humalog (insulin lispro) or Brand Insulin lispro

Brand Novolog (insulin aspart)

Lyumjev (insulin lispro)

Admelog (insulin lispro)

Apidra (insulin glulisine)

Fiasp (insulin aspart)

Product Name:Novolog Relion, Novolog Flexpen Relion, Novolog Mix 70/30 Relion, Novolog Mix 70/30 Flexpen Relion	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NOVOLOG FLEXPEN RELION	INSULIN ASPART SOLN PEN-INJECTOR 100 UNIT/ML	2710400200D220	Brand
NOVOLOG MIX 70/30 RELION	INSULIN ASPART PROT & ASPART (HUMAN) INJ 100 UNIT/ML (70-30)	27104070001820	Brand
NOVOLOG MIX 70/30 PREFILLED FLEXPEN RELION	INSULIN ASPART PROT & ASPART SUS PEN-INJ 100 UNIT/ML (70-30)	2710407000D320	Brand
NOVOLOG RELION	INSULIN ASPART INJ SOLN 100 UNIT/ML	27104002002022	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Both of the following:

2.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to Novolog/Novolog mix (insulin aspart) AND Fiasp (insulin aspart)

AND

2.2 Submission of medical records confirming Novolog/Novolog mix (insulin aspart) AND Fiasp (insulin aspart) have not been effective AND justification/rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternatives have not been shown to be effective despite having the same active ingredient

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure (of a minimum 30 day supply), contraindication, or intolerance to three of the following:

Brand Humalog (insulin lispro) or Brand Insulin lispro

Lyumjev (insulin lispro)

Admelog (insulin lispro)

Apidra (insulin glulisine)

Product Name:Novolin R Relion, Novolin N Relion, Novolin 70/30 Relion	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NOVOLIN R RELION	INSULIN REGULAR (HUMAN) INJ 100 UNIT/ML	27104010002005	Brand
NOVOLIN N RELION	INSULIN NPH (HUMAN) (ISOPHANE) INJ 100 UNIT/ML	27104020001805	Brand
NOVOLIN 70/30 RELION	INSULIN NPH ISOPHANE & REGULAR HUMAN INJ 100 UNIT/ML (70-30)	27104090001810	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Both of the following:

2.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced

intolerance (e.g., allergy to excipient) to Novolin/Novolin mix (human insulin) AND Humulin/Humulin mix (human insulin)

AND

2.2 Submission of medical records confirming Novolin/Novolin mix (human insulin) AND Humulin/Humulin mix (human insulin) have not been effective AND justification/rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternatives have not been shown to be effective despite having the same active ingredient

3 . References

Novolog Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. February 2023.

Humalog Prescribing Information. Lilly USA, LLC. Indianapolis, IN. August 2023.

Novolin Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. November 2022.

Lyumjev Prescribing Information. Lilly USA, LLC. Indianapolis, IN. October 2022.

Prior Authorization Guideline

Guideline ID	GL-228970
Guideline Name	Short-Acting Bronchodilators
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Proventil HFA (albuterol sulfate inhalation aerosol)
Bronchospasm Indicated in adults and children 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.
Drug Name: Xopenex HFA (levalbuterol tartrate inhalation aerosol)
Bronchospasm Indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.
Drug Name: Ventolin HFA, Proair HFA (albuterol sulfate inhalation aerosol), Proair Digihaler (albuterol sulfate inhalation powder), Proair Respiclick (albuterol sulfate powder)
Bronchospasm Indicated for the treatment of or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.

Exercise-Induced Bronchospasm Indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

2 . Criteria

Product Name:Proair Digihaler, Proair HFA, Proair Respiclick, Proventil HFA, Xopenex HFA, levalbuterol HFA, Ventolin HFA or Brand Albuterol HFA (Prasco manufacturer only, NDC 66993-0019-68)	
Approval Length	12 Months
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
PROVENTIL HFA	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT (90MCG BASE EQUIV)	44201010103410	Brand
XOPENEX HFA	LEVALBUTEROL TARTRATE INHAL AEROSOL 45 MCG/ACT (BASE EQUIV)	44201045503220	Brand
XOPENEX HFA	LEVALBUTEROL TARTRATE INHAL AEROSOL 45 MCG/ACT (BASE EQUIV)	44201045503220	Generic
LEVALBUTEROL TARTRATE HFA	LEVALBUTEROL TARTRATE INHAL AEROSOL 45 MCG/ACT (BASE EQUIV)	44201045503220	Generic
PROVENTIL HFA	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT (90MCG BASE EQUIV)	44201010103410	Generic
VENTOLIN HFA	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT (90MCG BASE EQUIV)	44201010103410	Generic
PROAIR HFA	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT (90MCG BASE EQUIV)	44201010103410	Generic
PROAIR RESPICLICK	ALBUTEROL SULFATE AER POW BA 108 MCG/ACT (90 MCG BASE EQUIV)	44201010108020	Brand
ALBUTEROL SULFATE HFA	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT (90MCG BASE EQUIV)	44201010103410	Generic
PROAIR DIGIHALER	ALBUTEROL SULFATE AER POW BA 108 MCG/ACT WITH SENSOR	44201010128020	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial (of a minimum 30-day supply) of generic albuterol HFA

3 . References

Proventil HFA [prescribing information]. Whitehouse Station, NJ: Merck & Co. Inc; October 2019.

Xopenex HFA [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; November 2023.

Ventolin HFA [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.

Proair HFA [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.

Proair Digihaler [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; February 2024.

Proair Respiclick [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229099
Guideline Name	Signifor, Signifor LAR (pasireotide) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Signifor LAR (pasireotide)
Acromegaly Indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option. **Cushing’s disease** Indicated for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.
Drug Name: Signifor (pasireotide)
Cushing's disease Indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

2 . Criteria

Product Name:Signifor LAR	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 10 MG (BASE EQUIV)	3017007540G210	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 20 MG (BASE EQUIV)	3017007540G220	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 30 MG (BASE EQUIV)	3017007540G225	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 40 MG (BASE EQUIV)	3017007540G230	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 60 MG (BASE EQUIV)	3017007540G240	Brand

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

Inadequate response to surgery

Patient is not a candidate for surgery

Product Name:Signifor LAR	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 10 MG (BASE EQUIV)	3017007540G210	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 20 MG (BASE EQUIV)	3017007540G220	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 30 MG (BASE EQUIV)	3017007540G225	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 40 MG (BASE EQUIV)	3017007540G230	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 60 MG (BASE EQUIV)	3017007540G240	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., patient's growth hormone level or insulin-like growth factor 1 level for age and gender has normalized/improved)

Product Name:Signifor, Signifor LAR	
Diagnosis	Cushing's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIGNIFOR	PASIREOTIDE DIASPARTATE INJ 0.3 MG/ML (BASE EQUIV)	30170075202020	Brand
SIGNIFOR	PASIREOTIDE DIASPARTATE INJ 0.6 MG/ML (BASE EQUIV)	30170075202030	Brand
SIGNIFOR	PASIREOTIDE DIASPARTATE INJ 0.9 MG/ML (BASE EQUIV)	30170075202040	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 10 MG (BASE EQUIV)	3017007540G210	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 20 MG (BASE EQUIV)	3017007540G220	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 30 MG (BASE EQUIV)	3017007540G225	Brand

SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 40 MG (BASE EQUIV)	3017007540G230	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 60 MG (BASE EQUIV)	3017007540G240	Brand

Approval Criteria

1 - Diagnosis of endogenous Cushing's disease

AND

2 - One of the following:

2.1 Pituitary surgery has not been curative for the patient

OR

2.2 Patient is not a candidate for pituitary surgery

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name:Signifor, Signifor LAR	
Diagnosis	Cushing's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIGNIFOR	PASIREOTIDE DIASPARTATE INJ 0.3 MG/ML (BASE EQUIV)	30170075202020	Brand
SIGNIFOR	PASIREOTIDE DIASPARTATE INJ 0.6 MG/ML (BASE EQUIV)	30170075202030	Brand

SIGNIFOR	PASIREOTIDE DIASPARTATE INJ 0.9 MG/ML (BASE EQUIV)	30170075202040	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 10 MG (BASE EQUIV)	3017007540G210	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 20 MG (BASE EQUIV)	3017007540G220	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 30 MG (BASE EQUIV)	3017007540G225	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 40 MG (BASE EQUIV)	3017007540G230	Brand
SIGNIFOR LAR	PASIREOTIDE PAMOATE FOR IM ER SUSP 60 MG (BASE EQUIV)	3017007540G240	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease)

Product Name:Signifor	
Diagnosis	Cushing's disease
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SIGNIFOR	PASIREOTIDE DIASPARTATE INJ 0.3 MG/ML (BASE EQUIV)	30170075202020	Brand
SIGNIFOR	PASIREOTIDE DIASPARTATE INJ 0.6 MG/ML (BASE EQUIV)	30170075202030	Brand
SIGNIFOR	PASIREOTIDE DIASPARTATE INJ 0.9 MG/ML (BASE EQUIV)	30170075202040	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of endogenous Cushing's disease

AND

2 - One of the following:

2.1 Pituitary surgery has not been curative for the patient

OR

2.2 Patient is not a candidate for pituitary surgery

AND

3 - Prescribed by or in consultation with an endocrinologist

3 . Background

Benefit/Coverage/Program Information
Quantity Limit These products are subject to an OptumRx standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.

4 . References

Signifor LAR Prescribing Information. Recordati Rare Diseases Inc. Bridgewater, NJ. July 2024.

Signifor Prescribing Information. Recordati Rare Diseases Inc. Bridgewater, NJ. July 2024.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228540
Guideline Name	Siklos (hydroxyurea)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Siklos (hydroxyurea)
Sickle Cell Anemia Indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in adult and pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises.

2 . Criteria

Product Name:Siklos	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIKLOS	HYDROXYUREA TAB 100 MG	82803030000320	Brand
SIKLOS	HYDROXYUREA TAB 1000 MG	82803030000340	Brand

Approval Criteria

1 - Diagnosis of sickle cell anemia

AND

2 - Patient has moderate to severe painful crises

AND

3 - Patient is 2 years of age or older

AND

4 - One of the following:

Patient is less than 18 years of age

Trial and failure, or intolerance to Droxia

3 . References

Siklos Prescribing Information. Addmedica, France. December 2021.

Prior Authorization Guideline

Guideline ID	GL-229075
Guideline Name	Siliq (brodalumab) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Siliq (brodalumab)
Plaque Psoriasis Indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

2 . Criteria

Product Name:Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SILIQ	BRODALUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 210 MG/1.5ML	9025052000E520	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

Greater than or equal to 3% body surface area involvement

Severe scalp psoriasis

Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to TWO of the following:

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product*

One formulary ustekinumab product*

Skyrizi (risankizumab)

Tremfya (guselkumab)

Otezla (apremilast)

Sotyktu (deucravacitinib)

OR

5.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

6 - Trial and failure, contraindication, or intolerance to BOTH of the following:

Bimzelx (bimekizumab-bkzx)

Cosentyx (secukinumab)

Notes	* For review process only: Refer to the table in the Background section for carrier-specific formulary products

Product Name:Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SILIQ	BRODALUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 210 MG/1.5ML	9025052000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

2 - Trial and failure, contraindication, or intolerance to BOTH of the following:

Bimzelx (bimekizumab-bkzx)

Cosentyx (secukinumab)

Product Name:Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SILIQ	BRODALUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 210 MG/1.5ML	9025052000E520	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

Greater than or equal to 3% body surface area involvement

Severe scalp psoriasis

Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to TWO of the following:

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product*

One formulary ustekinumab product*

Skyrizi (risankizumab)

Tremfya (guselkumab)

Otezla (apremilast)

Sotyktu (deucravacitinib)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to BOTH of the following:

Bimzelx (bimekizumab-bkzx)

Cosentyx (secukinumab)

Notes	* For review process only: Refer to the table in the Background section for carrier-specific formulary products

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products **Adalimumab-adaz** **Hyrimoz** **Hadlima** **Adalimumab-fkjp** **Formulary Ustekinumab Products** **Stelara**

4 . References

Siliq Prescribing Information. Valeant Pharmaceuticals Int. Bridgewater, NJ. April 2020.

Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

5 . Revision History

Date	Notes
12/20/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-229147
Guideline Name	Simponi, Simponi Aria (golimumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	6/3/2009
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Simponi (golimumab) - for subcutaneous use
Rheumatoid Arthritis (RA) In combination with methotrexate, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis. **Psoriatic Arthritis (PsA)** Alone or in combination with methotrexate, indicated for the treatment of adult patients with active psoriatic arthritis. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis. **Ulcerative Colitis (UC)** Indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine or 6-mercaptopurine for: (1) inducing and maintaining clinical response, (2)

improving endoscopic appearance of the mucosa during induction, (3) inducing clinical remission, and (4) achieving and sustaining clinical remission in induction responders.

Drug Name: Simponi Aria (golimumab) - for intravenous use

Rheumatoid Arthritis (RA) In combination with methotrexate, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

Polyarticular Juvenile Idiopathic Arthritis (PJIA) Indicated for the treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older.

Psoriatic Arthritis (PsA) Indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older.

Ankylosing Spondylitis (AS) Indicated for the treatment of adult patients with active ankylosing spondylitis.

2 . Criteria

Product Name:Simponi or Simponi Aria	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIMPONI ARIA	GOLIMUMAB IV SOLN 50 MG/4ML	66270040002015	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 50 MG/0.5ML	6627004000D520	
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML	6627004000E520	
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 100 MG/ML	6627004000D540	
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML	6627004000E540	

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [3, 4]:

methotrexate

leflunomide

sulfasalazine

AND

3 - Used in combination with methotrexate

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name:Simponi or Simponi Aria	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIMPONI ARIA	GOLIMUMAB IV SOLN 50 MG/4ML	66270040002015	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 50 MG/0.5ML	6627004000D520	
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML	6627004000E520	
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 100 MG/ML	6627004000D540	Brand

SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML	6627004000E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Simponi Aria	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIMPONI ARIA	GOLIMUMAB IV SOLN 50 MG/4ML	66270040002015	Brand

Approval Criteria

1 - Diagnosis of moderate to severely active PJIA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [5]:

leflunomide

methotrexate

Product Name:Simponi Aria	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIMPONI ARIA	GOLIMUMAB IV SOLN 50 MG/4ML	66270040002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [2, 5]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Simponi or Simponi Aria	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 50 MG/0.5ML	6627004000D520	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML	6627004000E520	Brand

SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 100 MG/ML	6627004000D540	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML	6627004000E540	Brand
SIMPONI ARIA	GOLIMUMAB IV SOLN 50 MG/4ML	66270040002015	Brand

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [6]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

Product Name:Simponi or Simponi Aria	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 50 MG/0.5ML	6627004000D520	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML	6627004000E520	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 100 MG/ML	6627004000D540	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML	6627004000E540	Brand
SIMPONI ARIA	GOLIMUMAB IV SOLN 50 MG/4ML	66270040002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 2, 6]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

Product Name:Simponi or Simponi Aria	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 50 MG/0.5ML	6627004000D520	
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML	6627004000E520	
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 100 MG/ML	6627004000D540	Brand

SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML	6627004000E540	Brand
SIMPONI ARIA	GOLIMUMAB IV SOLN 50 MG/4ML	66270040002015	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name:Simponi or Simponi Aria	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 50 MG/0.5ML	6627004000D520	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML	6627004000E520	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 100 MG/ML	6627004000D540	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML	6627004000E540	Brand
SIMPONI ARIA	GOLIMUMAB IV SOLN 50 MG/4ML	66270040002015	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 2, 7]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

Product Name:Simponi	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 50 MG/0.5ML	6627004000D520	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML	6627004000E520	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML	6627004000E540	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 100 MG/ML	6627004000D540	

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [8, 9]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, ESR, CRP)

Dependent on, or refractory to, corticosteroids

AND

3 - One of the following:

3.1 Patient is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)

OR

3.2 Trial and failure, contraindication, or intolerance to one of the following conventional therapies [1, 8, 9]

6-mercaptopurine

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

Azathioprine

Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Simponi	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 100 MG/ML	6627004000D540	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML	6627004000E540	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 50 MG/0.5ML	6627004000D520	Brand
SIMPONI	GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML	6627004000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 8, 9]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

3 . References

Simponi Prescribing Information. Janssen Biotech Inc. Horsham, PA. September 2019.

Simponi Aria Prescribing Information. Janssen Biotech, Inc. Horsham, PA. February 2021.

Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.

Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.

Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.

Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.

Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228542
Guideline Name	Skin Cancer Agents
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Klisyri (tirbanibulin) ointment
Actinic Keratosis indicated for the topical treatment of actinic keratosis on the face or scalp.

2 . Criteria

Product Name:Klisyri	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
KLISYRI	TIRBANIBULIN OINTMENT 1%	90374580004220	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to both of the following generics:

fluorouracil

imiquimod

3 . References

American Academy of Dermatology. Actinic Keratosis: diagnosis and treatment. https://www.aad.org/public/diseases/scaly-skin/actinic-keratosis#treatment. Accessed March 25, 2024.

Klisyri Prescribing Information. Almirall, LLC. Exton, PA. November 2023.

Skyclarys (omaveloxolone)

Prior Authorization Guideline

Guideline ID	GL-228972
Guideline Name	Skyclarys (omaveloxolone)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Skyclarys (omaveloxolone)
Friedreich's ataxia Indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

2 . Criteria

Product Name:Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYCLARYS	OMAVELOXOLONE CAP 50 MG	74135060000120	Brand

Approval Criteria

1 - Diagnosis of Friedreich's ataxia confirmed via genetic testing demonstrating mutation in the FXN gene

AND

2 - Patient is 16 years of age or older

AND

3 - Patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of greater than or equal to 20 and less than or equal to 80

AND

4 - Patient has a B-type natriuretic peptide value less than or equal to 200 pg/mL

AND

5 - Prescribed by or in consultation with one of the following:

Neurologist

Neurogeneticist

Physiatrist (Physical Medicine and Rehabilitation Specialist)

Product Name:Skyclarys	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYCLARYS	OMAVELOXOLONE CAP 50 MG	74135060000120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of less than or equal to 80 [A]

3 . Endnotes

Patients enrolled in the trial were those with an mFARS score between 20 and 80. There is no evidence of benefit for patients with severe neurologic dysfunction with an mFARS score of greater than 80.

4 . References

Skyclarys Prescribing Information. Reata Pharmaceuticals, Inc. Cambridge, MA. January 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228974
Guideline Name	Skyrizi (risankizumab-rzaa)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Skyrizi SC (risankizumab-rzaa)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of active psoriatic arthritis in adults. **Crohn's Disease (CD)** Indicated for the treatment of moderately to severely active Crohn's disease in adults. **Ulcerative Colitis (UC)** Indicated for the treatment of moderately to severely active ulcerative colitis in adults.
Drug Name: Skyrizi IV (risankizumab-rzaa)
Crohn's Disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adults.

2 . Criteria

Product Name:Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI PEN	RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150 MG/ML	9025057070D520	Brand
SKYRIZI	RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150 MG/ML	9025057070E540	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

Greater than or equal to 3% body surface area involvement

Severe scalp psoriasis

Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI PEN	RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150 MG/ML	9025057070D520	Brand
SKYRIZI	RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150 MG/ML	9025057070E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI PEN	RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150 MG/ML	9025057070D520	Brand
SKYRIZI	RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150 MG/ML	9025057070E540	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [4]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI PEN	RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150 MG/ML	9025057070D520	Brand
SKYRIZI	RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150 MG/ML	9025057070E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Skyrizi IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI	RISANKIZUMAB-RZAA IV SOLN 600 MG/10ML (60 MG/ML)	52504060702020	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - One of the following [5, 6]:

Frequent diarrhea and abdominal pain

At least 10% weight loss

Complications such as obstruction, fever, abdominal mass

Abnormal lab values (e.g., C-reactive protein [CRP])

CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [5, 6]:

6-mercaptopurine

Azathioprine

Methotrexate

Corticosteroid (e.g., prednisone)

AND

4 - Will be administered as an intravenous induction dose

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name:Skyrizi SC 180 mg, 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 180 MG/1.2ML	5250406070E210	Brand
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 360 MG/2.4ML	5250406070E220	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Skyrizi IV	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	3 month(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI	RISANKIZUMAB-RZAA IV SOLN 600 MG/10ML (60 MG/ML)	52504060702020	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein)

Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [7, 8]:

6-mercaptopurine

Azathioprine

Corticosteroid (e.g., prednisone)

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

AND

4 - Will be administered as an intravenous induction dose

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name:Skyrizi SC 180 mg, 360 mg	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 180 MG/1.2ML	5250406070E210	Brand
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 360 MG/2.4ML	5250406070E220	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name:Skyrizi SC 180 mg, 360 mg	
Diagnosis	Crohn's Disease (CD), Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 180 MG/1.2ML	5250406070E210	Brand
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 360 MG/2.4ML	5250406070E220	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5-8]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

Notes	If patient meets criteria above, please approve at GPI-14

3 . References

Skyrizi Prescribing Information. AbbVie, Inc. North Chicago, IL. June 2024.

Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.

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4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233277
Guideline Name	Sodium Oxybate Containing Agents - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	5/17/2011
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Xyrem (sodium oxybate) oral solution
Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1) Indicated for the treatment of cataplexy in patients 7 years of age and older with narcolepsy. **Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)** Indicated for the treatment of excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
Drug Name: Lumryz (sodium oxybate) extended-release oral solution
Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1) Indicated for the treatment of cataplexy in patients 7 years of age and older with narcolepsy. **Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)** Indicated for the treatment of excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

Drug Name: Xywav (calcium, magnesium, potassium, and sodium oxybates) oral solution
Narcolepsy with Cataplexy (Narcolepsy Type 1) Indicated for the treatment of cataplexy in patients 7 years of age and older with narcolepsy. **Narcolepsy without Cataplexy (Narcolepsy Type 2)** Indicated for the treatment of excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. **Idiopathic Hypersomnia (IH)** Indicated for the treatment of idiopathic hypersomnia (IH) in adults.

2 . Criteria

Product Name:Brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)*, Lumryz	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1) [2, 3, A, C, D]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SODIUM OXYBATE	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 4.5 GM	62450060203020	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 6 GM	62450060203025	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 7.5 GM	62450060203030	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 9 GM	62450060203035	Brand
LUMRYZ STARTER PACK	SODIUM OXYBATE PACK FOR ER SUSP 4.5 & 6 & 7.5 GM STARTER PAK	6245006020B120	Brand

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

2 - Symptoms of cataplexy are present

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - Patient is 7 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Notes	*If member meets criteria above, please approve at NDC level.

Product Name:Brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)*, Lumryz	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

SODIUM OXYBATE	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 4.5 GM	62450060203020	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 6 GM	62450060203025	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 7.5 GM	62450060203030	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 9 GM	62450060203035	Brand
LUMRYZ STARTER PACK	SODIUM OXYBATE PACK FOR ER SUSP 4.5 & 6 & 7.5 GM STARTER PAK	6245006020B120	Brand

Approval Criteria

1 - Patient demonstrates a reduction in the frequency of cataplexy attacks associated with therapy

OR

2 - Patient demonstrates a reduction in symptoms of excessive daytime sleepiness associated with therapy

Notes	*If member meets criteria above, please approve at NDC level.

Product Name:Brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)*, Lumryz	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2) [2, 3, B, C, E]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SODIUM OXYBATE	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 4.5 GM	62450060203020	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 6 GM	62450060203025	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 7.5 GM	62450060203030	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 9 GM	62450060203035	Brand

LUMRYZ STARTER PACK	SODIUM OXYBATE PACK FOR ER SUSP 4.5 & 6 & 7.5 GM STARTER PAK	6245006020B120	Brand

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

2 - Symptoms of cataplexy are absent

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - Patient is 7 years of age or older

AND

5 - BOTH of the following:

5.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to both of the following:

Generic modafinil or armodafinil

Sunosi

AND

5.2 ONE of the following

5.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

5.2.2 Patient is not a candidate

AND

6 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Notes	*If member meets criteria above, please approve at NDC level.

Product Name:Brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)*, Lumryz	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SODIUM OXYBATE	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 4.5 GM	62450060203020	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 6 GM	62450060203025	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 7.5 GM	62450060203030	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 9 GM	62450060203035	Brand
LUMRYZ STARTER PACK	SODIUM OXYBATE PACK FOR ER SUSP 4.5 & 6 & 7.5 GM STARTER PAK	6245006020B120	Brand

Approval Criteria

1 - Patient demonstrates a reduction in symptoms of excessive daytime sleepiness associated with therapy

AND

2 - BOTH of the following:

2.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to both of the following:

Generic modafinil or armodafinil

Sunosi

AND

2.2 ONE of the following

2.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

2.2.2 Patient is not a candidate

Notes	*If member meets criteria above, please approve at NDC level.

Product Name:Xyrem, Brand Sodium Oxybate (Amneal manufacturer only, NDC 69238-2391-01)	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1) [2, 3, A, C, D]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SODIUM OXYBATE	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic
XYREM	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

2 - Symptoms of cataplexy are present

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - Patient is 7 years of age or older

AND

5 - Trial and failure, or intolerance to brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)

AND

6 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Xyrem, Brand Sodium Oxybate (Amneal manufacturer only, NDC 69238-2391-01)	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SODIUM OXYBATE	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic
XYREM	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic

Approval Criteria

1 - One of the following:

1.1 Patient demonstrates a reduction in the frequency of cataplexy attacks associated with therapy

OR

1.2 Patient demonstrates a reduction in symptoms of excessive daytime sleepiness associated with therapy

AND

2 - Trial and failure, or intolerance to brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)

Product Name:Xyrem, Brand Sodium Oxybate (Amneal manufacturer only, NDC 69238-2391-01)

Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2) [2, 3, B, C, E]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SODIUM OXYBATE	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic
XYREM	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

2 - Symptoms of cataplexy are absent

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - Patient is 7 years of age or older

AND

5 - BOTH of the following:

5.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to both of the following:

Generic modafinil or armodafinil

Sunosi

AND

5.2 ONE of the following

5.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

5.2.2 Patient is not a candidate

AND

6 - Trial and failure, or intolerance to brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)

AND

7 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Xyrem, Brand Sodium Oxybate (Amneal manufacturer only, NDC 69238-2391-01)	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SODIUM OXYBATE	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic
XYREM	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic

Approval Criteria

1 - Patient demonstrates a reduction in symptoms of excessive daytime sleepiness associated with therapy

AND

2 - Both of the following:

2.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to both of the following:

Generic modafinil or armodafinil

Sunosi

AND

2.2 ONE of the following

2.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

2.2.2 Patient is not a candidate

AND

3 - Trial and failure, or intolerance to brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)

Product Name:Xyrem, brand Sodium Oxybate (Amneal manufacturer only, NDC 69238-2391-01)	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1) [2, 3, A, C, D]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SODIUM OXYBATE	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic
XYREM	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

2 - Symptoms of cataplexy are present

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - Patient is 7 years of age or older

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)

AND

6 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Xyrem, Brand Sodium Oxybate (Amneal manufacturer only, NDC 69238-2391-01)	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2) [2, 3, B, C, E]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SODIUM OXYBATE	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic
XYREM	SODIUM OXYBATE ORAL SOLUTION 500 MG/ML	62450060202020	Generic

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

2 - Symptoms of cataplexy are absent

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - Patient is 7 years of age or older

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming both of the following:

5.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to both of the following:

Generic modafinil or armodafinil

Sunosi

AND

5.2 ONE of the following

5.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

5.2.2 Patient is not a candidate

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)

AND

7 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Lumryz	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1) [2, 3, 12, A, C, D]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 4.5 GM	62450060203020	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 6 GM	62450060203025	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 7.5 GM	62450060203030	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 9 GM	62450060203035	Brand
LUMRYZ STARTER PACK	SODIUM OXYBATE PACK FOR ER SUSP 4.5 & 6 & 7.5 GM STARTER PAK	6245006020B120	Brand

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

2 - Symptoms of cataplexy are present

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - Patient is 7 years of age or older

AND

5 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to TWO of the following:

Brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)

Xywav

Wakix

AND

6 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Lumryz	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2) [2, 3, 12, B, C, E]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 4.5 GM	62450060203020	Brand

LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 6 GM	62450060203025	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 7.5 GM	62450060203030	Brand
LUMRYZ	SODIUM OXYBATE PACK FOR ORAL ER SUSP 9 GM	62450060203035	Brand
LUMRYZ STARTER PACK	SODIUM OXYBATE PACK FOR ER SUSP 4.5 & 6 & 7.5 GM STARTER PAK	6245006020B120	Brand

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

2 - Symptoms of cataplexy are absent

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - Patient is 7 years of age or older

AND

5 - BOTH of the following:

5.1 Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to THREE of the following:

Generic modafinil or armodafinil

Sunosi

Wakix

Brand Sodium Oxybate (Hikma manufacturer only, NDC 00054-9628-57)

Xywav

AND

5.2 ONE of the following

5.2.1 Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

5.2.2 Submission of medical records (e.g., chart notes) confirming patient is not a candidate

AND

6 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Xywav	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1) [F]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XYWAV	CALCIUM, MAG, POTASSIUM, & SOD OXYBATES ORAL SOLN 500 MG/ML	62459904202020	Brand

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [14-18]

AND

2 - Symptoms of cataplexy are present [18]

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present [18]

AND

4 - Patient is 7 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Xywav	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XYWAV	CALCIUM, MAG, POTASSIUM, & SOD OXYBATES ORAL SOLN 500 MG/ML	62459904202020	Brand

Approval Criteria

1 - Patient demonstrates a reduction in the frequency of cataplexy attacks associated with therapy

OR

2 - Patient demonstrates a reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name:Xywav	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2) [G]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XYWAV	CALCIUM, MAG, POTASSIUM, & SOD OXYBATES ORAL SOLN 500 MG/ML	62459904202020	Brand

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [14-18]

AND

2 - Symptoms of cataplexy are absent [18]

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present [18]

AND

4 - Patient is 7 years of age or older

AND

5 - Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to both of the following : [14-18]

generic modafinil or generic armodafinil

Sunosi

AND

6 - One of the following:

6.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant [14-18]

OR

6.2 Patient is not a candidate

AND

7 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Xywav	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XYWAV	CALCIUM, MAG, POTASSIUM, & SOD OXYBATES ORAL SOLN 500 MG/ML	62459904202020	Brand

Approval Criteria

1 - Patient demonstrates a reduction in symptoms of excessive daytime sleepiness associated with therapy

AND

2 - Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to both of the following :

generic modafinil or generic armodafinil

Sunosi

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

3.2 Patient is not a candidate

Product Name:Xywav	
Diagnosis	Idiopathic Hypersomnia (IH) [H]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XYWAV	CALCIUM, MAG, POTASSIUM, & SOD OXYBATES ORAL SOLN 500 MG/ML	62459904202020	Brand

Approval Criteria

1 - Diagnosis of idiopathic hypersomnia as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [14-18]

AND

2 - Symptoms of excessive daytime sleepiness (e.g., nap duration of longer than 60 minutes) are present [18]

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Xywav	
Diagnosis	Idiopathic Hypersomnia (IH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XYWAV	CALCIUM, MAG, POTASSIUM, & SOD OXYBATES ORAL SOLN 500 MG/ML	62459904202020	Brand

Approval Criteria

1 - Patient demonstrates a reduction in symptoms of excessive daytime sleepiness associated with therapy

3 . Endnotes

International classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy with cataplexy (narcolepsy type 1) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. One or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT); or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than 110 pg/mL or one-third of the normative values with the same standardized assay). 3. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [4-6]

International classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy without cataplexy (narcolepsy type 2) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. Cataplexy is absent 3. CSF hypocretin-1 levels, if measured, must not meet the narcolepsy type 1 criterion. 4. A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the

SOREMPs on the MSLT). 5. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [4-6]

Narcolepsy is often misdiagnosed. Treatment can often be given for the wrong reason if the patient has another condition with symptoms of excessive sleepiness. The diagnosis is the most important, and should be the focus in determining appropriate treatment. Both clinical symptoms and sleep study criteria (both daytime and nighttime tests) are needed to guide the diagnosis. [7]

Xyrem is very effective and can be considered a first-line treatment for cataplexy in patients with narcolepsy (narcolepsy type 1). Antidepressants have mixed issues. Currently, there are no safety data with antidepressants for the treatment of cataplexy, and tricyclics and SSRIs cause a lot of side effects including anticholinergic effects, sedation, impotence and EKG changes. Xyrem offers the advantage of treating cataplexy, and giving the patient more energy without the side effects compared to antidepressants. [7]

Generally, modafinil or armodafinil is given first for excessive daytime sleepiness without cataplexy (narcolepsy type 2), followed by on-demand stimulants, then by Xyrem. There are no head-to-head trials with Xyrem, but anecdotal and clinical practice reports find that patients receive a similar response as with modafinil/armodafinil, but not as good as stimulants for excessive daytime sleepiness. [7]

International classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy with cataplexy (narcolepsy type 1) : 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. Presence of one or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT); or cerebrospinal fluid (CSF) hypocretin-1 concentration is less than or equal to 110 pg/mL or less than one-third of the mean values obtained in normal subjects with the same standardized assay). 3. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [14-18]

International classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy without cataplexy (narcolepsy type 2) : 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. Cataplexy is absent 3. CSF hypocretin-1 levels, if measured, is greater than 110 pg/mL or greater than one-third of the mean values obtained in normal subjects with the same standardized assay) 4. A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on

the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT). 5. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [14-18]

International classification of Sleep Disorders (ICSD-3) diagnostic criteria for idiopathic hypersomnia requires all of the following: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months 2. Cataplexy is absent 3. A multiple sleep latency test (MSLT) documents fewer than two sleep-onset rapid eye movement periods (SOREMPs), or no SOREMPs if the REM sleep latency on the preceding polysomnogram was ≤15 minutes 4. The presence of at least one of the following: MSLT shows a mean sleep latency of ≤8 minutes or Total 24-hour sleep time is ≥660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log 5. Insufficient sleep syndrome is ruled out (if deemed necessary, by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed, preferably confirmed by at least a week of wrist actigraphy) 6. No better explanation by another sleep disorder, medical or psychiatric disorder or use of drugs or medications. [14-18]

4 . References

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Xywav Prescribing Information. Jazz Pharmaceuticals, Inc. Palo Alto, CA. August 2022.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Sohonos (palovarotene)

Prior Authorization Guideline

Guideline ID	GL-233192
Guideline Name	Sohonos (palovarotene)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/16/2023
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Sohonos (palovarotene)
Fibrodysplasia Ossificans Progressiva (FOP) Indicated for reduction in the volume of new heterotopic ossification in adults and children aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP).

2 . Criteria

Product Name:Sohonos	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOHONOS	PALOVAROTENE CAP 1 MG	75886060000120	Brand
SOHONOS	PALOVAROTENE CAP 1.5 MG	75886060000125	Brand
SOHONOS	PALOVAROTENE CAP 2.5 MG	75886060000130	Brand
SOHONOS	PALOVAROTENE CAP 5 MG	75886060000135	Brand
SOHONOS	PALOVAROTENE CAP 10 MG	75886060000140	Brand

Approval Criteria

1 - Diagnosis of Fibrodysplasia Ossificans Progressiva (FOP)

AND

2 - Molecular genetic testing confirms mutation in the ACVR1 gene

AND

3 - One of the following:

3.1 Both of the following:

Patient is female

Patient is 8 years of age or older

OR

3.2 Both of the following:

Patient is male

Patient is 10 years of age or older

AND

4 - Prescribed by or in consultation with one of the following: [8]

Geneticist

Orthopedic physician

Rheumatologist

Endocrinologist

Product Name:Sohonos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOHONOS	PALOVAROTENE CAP 1 MG	75886060000120	Brand
SOHONOS	PALOVAROTENE CAP 1.5 MG	75886060000125	Brand
SOHONOS	PALOVAROTENE CAP 2.5 MG	75886060000130	Brand
SOHONOS	PALOVAROTENE CAP 5 MG	75886060000135	Brand
SOHONOS	PALOVAROTENE CAP 10 MG	75886060000140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction of volume in new abnormal bone growth)

3 . References

Sohonos Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. August 2023.

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Clinical Consult. October 27, 2023.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228977
Guideline Name	Soliris (eculizumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Soliris (eculizumab)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. **Atypical Hemolytic Uremic Syndrome (aHUS)** Indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. Limitations of Use: Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). **Generalized Myasthenia Gravis (gMG)** Indicated for the treatment of adult patients with generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody positive. **Neuromyelitis Optica Spectrum Disorder (NMOSD)** Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name:Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

Product Name:Soliris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS)

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

3 - Prescribed by or in consultation with one of the following:

Hematologist

Nephrologist

Product Name:Soliris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response (e.g., increase in mean platelet counts, hematologic normalization) to therapy

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

Product Name:Soliris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - Trial and failure, contraindication, or intolerance to one of the following:

Ultomiris (ravulizumab)

Vyvgart (efgartigimod)

AND

4 - One of the following: [2, 3]

4.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

4.2 Both of the following:

4.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

4.2.2 Trial and failure, contraindication, or intolerance to one of the following:

Chronic plasmapheresis or plasma exchange (PE)

Intravenous immunoglobulin (IVIG)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Soliris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and failure, contraindication, or intolerance to one of the following:

Ultomiris (ravulizumab)

Vyvgart (efgartigimod)

Product Name:Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Ophthalmologist

Product Name:Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria
1 - Patient demonstrates positive clinical response to therapy

3 . References

Soliris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. November 2020.

Howard JF Jr, Utsugisawa K, Benatar M, et al. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study. Lancet Neurol. 2017;16(12):976-986.

Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233287
Guideline Name	Somatuline Depot (lanreotide)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/13/2007
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Somatuline Depot (lanreotide)
Acromegaly Indicated for the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal. **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)** Indicated for the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival. **Carcinoid Syndrome** Indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
Drug Name: Lanreotide Injection

Acromegaly Indicated for the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal.

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) Indicated for the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

Off Label Uses: Carcinoid Syndrome [3] Indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

2 . Criteria

Product Name:Brand Somatuline Depot, Generic lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOMATULINE DEPOT	LANREOTIDE ACETATE EXTENDED RELEASE INJ 60 MG/0.2ML	30170050102025	Brand
SOMATULINE DEPOT	LANREOTIDE ACETATE EXTENDED RELEASE INJ 90 MG/0.3ML	30170050102030	Brand
SOMATULINE DEPOT	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Brand
LANREOTIDE ACETATE	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Generic

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

Surgery

Radiotherapy

OR

2.2 Not a candidate for one of the following:

Surgery

Radiotherapy

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name:Brand Somatuline Depot, Generic lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOMATULINE DEPOT	LANREOTIDE ACETATE EXTENDED RELEASE INJ 60 MG/0.2ML	30170050102025	Brand
SOMATULINE DEPOT	LANREOTIDE ACETATE EXTENDED RELEASE INJ 90 MG/0.3ML	30170050102030	Brand
SOMATULINE DEPOT	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Brand

LANREOTIDE ACETATE	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy, such as a reduction or normalization of IGF-1/GH level for same age and sex

Product Name:Brand Somatuline Depot 120mg/0.5mL, Generic lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOMATULINE DEPOT	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Brand
LANREOTIDE ACETATE	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Generic

Approval Criteria

1 - Diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET)

AND

2 - Disease is one of the following:

Unresectable, locally advanced

Metastatic

Product Name:Brand Somatuline Depot 120mg/0.5mL, Generic lanreotide 120mg/0.5ml

Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOMATULINE DEPOT	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Brand
LANREOTIDE ACETATE	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Somatuline Depot 120mg/0.5mL, Generic lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOMATULINE DEPOT	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Brand
LANREOTIDE ACETATE	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Generic

Approval Criteria

1 - Diagnosis of carcinoid syndrome

AND

2 - Used to reduce the frequency of short-acting somatostatin analog rescue therapy

AND

3 - Prescribed by or in consultation with one of the following:

Endocrinologist

Oncologist

Product Name:Brand Somatuline Depot 120mg/0.5mL, Generic lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOMATULINE DEPOT	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Brand
LANREOTIDE ACETATE	LANREOTIDE ACETATE EXTENDED RELEASE INJ 120 MG/0.5ML	30170050102040	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

Somatuline Depot Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. July 2024.

Lanreotide Injection Prescribing Information. Cipla USA Inc. Warren, NJ. July 2024.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-229134
Guideline Name	Somavert (pegvisomant)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	7/14/2006
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Somavert (pegvisomant)
Acromegaly Indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-1 (IGF-1) levels.

2 . Criteria

Product Name:Somavert	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOMAVERT	PEGVISOMANT FOR INJ 10 MG (AS PROTEIN)	30180060002120	Brand
SOMAVERT	PEGVISOMANT FOR INJ 15 MG (AS PROTEIN)	30180060002130	Brand
SOMAVERT	PEGVISOMANT FOR INJ 20 MG (AS PROTEIN)	30180060002140	Brand
SOMAVERT	PEGVISOMANT FOR INJ 25 MG (AS PROTEIN)	30180060002150	Brand
SOMAVERT	PEGVISOMANT FOR INJ 30 MG (AS PROTEIN)	30180060002160	Brand

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following: [2]

2.1 Inadequate response to one of the following:

Surgery

Radiation therapy

Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

2.2 Not a candidate for all of the following:

Surgery

Radiation therapy

Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

AND

3 - One of the following: [2]

3.1 Inadequate response, contraindication, or intolerance to a somatostatin analog (e.g., octreotide, Somatuline [lanreotide])

OR

3.2 Clinical rationale provided for preferred treatment with pegvisomant (e.g., comorbid diabetes mellitus is present with acromegaly)

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name:Somavert	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOMAVERT	PEGVISOMANT FOR INJ 10 MG (AS PROTEIN)	30180060002120	Brand
SOMAVERT	PEGVISOMANT FOR INJ 15 MG (AS PROTEIN)	30180060002130	Brand
SOMAVERT	PEGVISOMANT FOR INJ 20 MG (AS PROTEIN)	30180060002140	Brand
SOMAVERT	PEGVISOMANT FOR INJ 25 MG (AS PROTEIN)	30180060002150	Brand
SOMAVERT	PEGVISOMANT FOR INJ 30 MG (AS PROTEIN)	30180060002160	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (such as biochemical control, decrease or normalization of IGF-1 levels)

3 . References

Somavert Prescribing Information. Pharmacia & Upjohn Company LLC. New York, NY. July 2023.

Katznelson L, Laws ER Jr, Melmed S, Molitch ME, Murad MH, Utz A, Wass JA. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99(11):3933-51.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Sotyktu (deucravacitinib)

Prior Authorization Guideline

Guideline ID	GL-229089
Guideline Name	Sotyktu (deucravacitinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Sotyktu	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOTYKTU	DEUCRAVACITINIB TAB 6 MG	90250524000320	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

At least 3% body surface area (BSA) involvement

Severe scalp psoriasis

Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Trial and failure, contraindication, or intolerance to TWO of the following:

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product*

Skyrizi (risankizumab-rzaa)

Stelara (ustekinumab)

Tremfya (guselkumab)

Otezla (apremilast)

AND

6 - Not used in combination with other potent immunosuppressants (e.g., azathioprine, cyclosporine, biologic disease-modifying antirheumatic drugs [DMARDs])

Notes	* For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products

Product Name:Sotyktu	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOTYKTU	DEUCRAVACITINIB TAB 6 MG	90250524000320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

2 - Not used in combination with other potent immunosuppressants (e.g., azathioprine, cyclosporine, biologic DMARDs)

2 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products **Adalimumab-adaz** **Hyrimoz** **Hadlima** **Adalimumab-fkjp**

3 . References

Sotyktu Prescribing Information. Bristol-Myers Squibb Co. Princeton, NJ. September 2022.

Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

4 . Revision History

Date	Notes
12/23/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-228980
Guideline Name	Sovaldi (sofosbuvir)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sovaldi (sofosbuvir)
Chronic Hepatitis C (CHC) ADULT PATIENTS: Indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen. - Genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin. - Genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin. PEDIATRIC PATIENTS: Indicated for the treatment of chronic HCV genotype 2 or 3 infection in pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

2 . Criteria

Product Name:Sovaldi

Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1 or 4 - Sovaldi Plus Peginterferon Plus Ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOVALDI	SOFOSBUVIR TAB 200 MG	12353080000310	Brand
SOVALDI	SOFOSBUVIR TAB 400 MG	12353080000320	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 150 MG	12353080003015	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 200 MG	12353080003020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1 or 4

AND

2 - Used in combination with peginterferon alfa and ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name:Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2 - Sovaldi Plus Ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOVALDI	SOFOSBUVIR TAB 200 MG	12353080000310	Brand
SOVALDI	SOFOSBUVIR TAB 400 MG	12353080000320	Brand

SOVALDI	SOFOSBUVIR PELLET PACK 150 MG	12353080003015	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 200 MG	12353080003020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 2 infection

AND

2 - Used in combination with ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

Epclusa (sofosbuvir/velpatasvir)

Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name:Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 3 - Sovaldi Plus Ribavirin
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOVALDI	SOFOSBUVIR TAB 200 MG	12353080000310	Brand
SOVALDI	SOFOSBUVIR TAB 400 MG	12353080000320	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 150 MG	12353080003015	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 200 MG	12353080003020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 3 infection

AND

2 - Used in combination with ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

Epclusa (sofosbuvir/velpatasvir)

Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name:Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Mavyret)

Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOVALDI	SOFOSBUVIR TAB 200 MG	12353080000310	Brand
SOVALDI	SOFOSBUVIR TAB 400 MG	12353080000320	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 150 MG	12353080003015	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 200 MG	12353080003020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Mavyret (glecaprevir/pibrentasvir) [2]

AND

3 - Used in combination with Mavyret (glecaprevir/pibrentasvir) and ribavirin [2]

AND

4 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

Product Name:Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Vosevi)
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOVALDI	SOFOSBUVIR TAB 200 MG	12353080000310	Brand
SOVALDI	SOFOSBUVIR TAB 400 MG	12353080000320	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 150 MG	12353080003015	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 200 MG	12353080003020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [2]

AND

3 - Used in combination with Mavyret (glecaprevir/pibrentasvir) and ribavirin [2]

AND

4 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

3 . References

Sovaldi Prescribing Information. Gilead Sciences, Inc. Foster City, CA. March 2020.

American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228982
Guideline Name	Spevigo (spesolimab-sbzo)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Spevigo (spesolimab-sbzo)
Generalized Pustular Psoriasis (GPP) Indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.

2 . Criteria

Product Name:Spevigo IV	
Approval Length	14 Days [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPEVIGO	SPESOLIMAB-SBZO IV SOLN 450 MG/7.5ML (60 MG/ML)	90250577702050	Brand

Approval Criteria

1 - Diagnosis of generalized pustular psoriasis (GPP)

AND

2 - Patient has a moderate to severe GPP flare based on one of the following:

Presence of fresh pustules (new appearance or worsening of pustules)

At least 5% of body surface area (BSA) covered with erythema and the presence of pustules

A Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) [B]

GPPPGA pustulation sub score of at least 2 (mild)

AND

3 - Both of the following:

Patient is 12 years of age or older

Patient weighs at least 40kg

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Patient has not already received two infusions of Spevigo for a single flare

Product Name:Spevigo SC	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPEVIGO	SPESOLIMAB-SBZO SUBCUTANEOUS SOLN PREF SYR 150 MG/ML	9025057770E530	Brand

Approval Criteria

1 - Diagnosis of generalized pustular psoriasis (GPP) as defined by both of the following [2]:

Primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques)

Disease is relapsing (>1 episode) or persistent (>3 months)

AND

2 - Subcutaneous formulation will not be used to treat GPP flare

AND

3 - Both of the following:

Patient is 12 years of age or older

Patient weighs at least 40kg

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Spevigo SC	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPEVIGO	SPESOLIMAB-SBZO SUBCUTANEOUS SOLN PREF SYR 150 MG/ML	9025057770E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in number of flares)

3 . Endnotes

Spevigo is administered as a single intravenous infusion. If GPP flare symptoms persist, an additional intravenous dose may be administered one week after the initial dose [1].

The total Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score ranges from 0 (clear) to 4 (severe) [1].

4 . References

Spevigo Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. March 2024.

Navarini AA, Burden AD, Capon F, Mrowietz U, Puig L, Köks S, Kingo K, Smith C, Barker JN1.2. Navarini AA, Burden AD, Capon F, et al; ERASPEN Network. European consensus statement on phenotypes of pustular psoriasis. J Eur Acad Dermatol Venereol. 2017 Nov;31(11):1792-1799. doi: 10.1111/jdv.14386. Epub 2017 Aug 29.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228720
Guideline Name	Spravato (esketamine) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Spravato (esketamine)
Depression Indicated, in conjunction with an oral antidepressant, for the treatment of: - Treatment-resistant depression (TRD) in adults - Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior. Limitations of Use: The effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of Spravato does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of Spravato. Spravato is not approved as an anesthetic agent. The safety and effectiveness of Spravato as an anesthetic agent have not been established.

2 . Criteria

Product Name:Spravato

Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPRAVATO 56MG DOSE	ESKETAMINE HCL NASAL SOLN 28 MG/DEVICE X 2 (56 MG DOSE PACK)	5811002010C520	Brand
SPRAVATO 84MG DOSE	ESKETAMINE HCL NASAL SOLN 28 MG/DEVICE X 3 (84 MG DOSE PACK)	5811002010C530	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

Diagnosis of major depressive disorder

Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode [1-5, A, B]

OR

1.2 Both of the following:

1.2.1 Diagnosis of major depressive disorder

AND

1.2.2 Patient has both of the following:

Depressive symptoms

Acute suicidal ideation or behavior

AND

2 - Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline)

AND

3 - Prescribed by or in consultation with a psychiatrist

Product Name:Spravato	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPRAVATO 56MG DOSE	ESKETAMINE HCL NASAL SOLN 28 MG/DEVICE X 2 (56 MG DOSE PACK)	5811002010C520	Brand
SPRAVATO 84MG DOSE	ESKETAMINE HCL NASAL SOLN 28 MG/DEVICE X 3 (84 MG DOSE PACK)	5811002010C530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

AND

2 - Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline)

Product Name:Spravato	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SPRAVATO 56MG DOSE	ESKETAMINE HCL NASAL SOLN 28 MG/DEVICE X 2 (56 MG DOSE PACK)	5811002010C520	Brand
SPRAVATO 84MG DOSE	ESKETAMINE HCL NASAL SOLN 28 MG/DEVICE X 3 (84 MG DOSE PACK)	5811002010C530	Brand

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g. chart notes) documenting Both of the following:

Diagnosis of major depressive disorder

Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode [1-5, A, B]

OR

1.2 Submission of medical records (e.g. chart notes) documenting Both of the following:

1.2.1 Diagnosis of major depressive disorder

AND

1.2.2 Patient has both of the following:

Depressive symptoms

Acute suicidal ideation or behavior

AND

2 - Submission of medical records (e.g. chart notes) or paid claims documenting use in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline)

AND

3 - Prescribed by or in consultation with a psychiatrist

3 . Endnotes

According to the American Psychiatric Association, generally, 4–8 weeks of treatment are needed before concluding that a patient is partially responsive or unresponsive to a specific intervention. [2]

Per clinical consults with psychiatrists: A trial of antidepressants should include different classes (mechanisms of action) when defining treatment resistance. [4-5]

4 . References

Spravato Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. July 2020.

American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder (3rd Edition). October 2010. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Accessed March 31, 2022.

Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006;163(11):1905-17.

Per clinical consult with psychiatrist, April 25, 2019.

Per clinical consult with psychiatrist, April 18, 2019.

Sprycel (dasatinib)

Prior Authorization Guideline

Guideline ID	GL-233246
Guideline Name	Sprycel (dasatinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/3/2006
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Sprycel (dasatinib)
Newly diagnosed Chronic Myeloid Leukemia Indicated for the treatment of adults with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. **Resistant or intolerant Chronic Myeloid Leukemia** Indicated for the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. **Acute Lymphoblastic Leukemia (ALL)** Indicated for the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy. **Pediatric ALL** Indicated for the treatment of pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.

Pediatric Patients with Ph+ CML Indicated for the treatment of pediatric patients 1 year of age and older with Ph+ CML in chronic phase.

2 . Criteria

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	Philadelphia chromosome-positive/BCR ABL positive (Ph+/BCR ABL) Acute Lymphoblastic Leukemia/Acute Lymphoblastic Lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPRYCEL	DASATINIB TAB 20 MG	21531820000320	Brand
SPRYCEL	DASATINIB TAB 50 MG	21531820000340	Brand
SPRYCEL	DASATINIB TAB 70 MG	21531820000350	Brand
SPRYCEL	DASATINIB TAB 80 MG	21531820000354	Brand
SPRYCEL	DASATINIB TAB 100 MG	21531820000360	Brand
SPRYCEL	DASATINIB TAB 140 MG	21531820000380	Brand
DASATINIB	DASATINIB TAB 20 MG	21531820000320	Generic
DASATINIB	DASATINIB TAB 50 MG	21531820000340	Generic
DASATINIB	DASATINIB TAB 70 MG	21531820000350	Generic
DASATINIB	DASATINIB TAB 80 MG	21531820000354	Generic
DASATINIB	DASATINIB TAB 100 MG	21531820000360	Generic
DASATINIB	DASATINIB TAB 140 MG	21531820000380	Generic

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL acute lymphoblastic leukemia (ALL)

AND

2 - Trial and failure, or intolerance to generic dasatinib (applies to Brand Sprycel only)

AND

3 - One of the following (applies to Brand Sprycel only)

3.1 Trial and failure, contraindication, or intolerance to generic imatinib

OR

3.2 Continuation of prior therapy

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	Ph+/BCR ABL Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPRYCEL	DASATINIB TAB 20 MG	21531820000320	Brand
SPRYCEL	DASATINIB TAB 50 MG	21531820000340	Brand
SPRYCEL	DASATINIB TAB 70 MG	21531820000350	Brand
SPRYCEL	DASATINIB TAB 80 MG	21531820000354	Brand
SPRYCEL	DASATINIB TAB 100 MG	21531820000360	Brand
SPRYCEL	DASATINIB TAB 140 MG	21531820000380	Brand
DASATINIB	DASATINIB TAB 20 MG	21531820000320	Generic
DASATINIB	DASATINIB TAB 50 MG	21531820000340	Generic
DASATINIB	DASATINIB TAB 70 MG	21531820000350	Generic
DASATINIB	DASATINIB TAB 80 MG	21531820000354	Generic

DASATINIB	DASATINIB TAB 100 MG	21531820000360	Generic
DASATINIB	DASATINIB TAB 140 MG	21531820000380	Generic

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL chronic myelogenous/myeloid leukemia (CML)

AND

2 - Trial and failure, or intolerance to generic dasatinib (applies to Brand Sprycel only)

AND

3 - One of the following: (applies to Brand Sprycel only)

3.1 Trial and failure, contraindication, or intolerance to generic imatinib

OR

3.2 Continuation of prior therapy

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPRYCEL	DASATINIB TAB 20 MG	21531820000320	Brand
SPRYCEL	DASATINIB TAB 50 MG	21531820000340	Brand
SPRYCEL	DASATINIB TAB 70 MG	21531820000350	Brand
SPRYCEL	DASATINIB TAB 80 MG	21531820000354	Brand

SPRYCEL	DASATINIB TAB 100 MG	21531820000360	Brand
SPRYCEL	DASATINIB TAB 140 MG	21531820000380	Brand
DASATINIB	DASATINIB TAB 20 MG	21531820000320	Generic
DASATINIB	DASATINIB TAB 50 MG	21531820000340	Generic
DASATINIB	DASATINIB TAB 70 MG	21531820000350	Generic
DASATINIB	DASATINIB TAB 80 MG	21531820000354	Generic
DASATINIB	DASATINIB TAB 100 MG	21531820000360	Generic
DASATINIB	DASATINIB TAB 140 MG	21531820000380	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure, or intolerance to generic dasatinib (applies to Brand Sprycel only)

AND

3 - One of the following: (applies to Brand Sprycel only)

3.1 Trial and failure, contraindication, or intolerance to generic imatinib

OR

3.2 Continuation of prior therapy

3 . References

Sprycel [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; February 2023.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic Myeloid Leukemia v.1.2023. Available by subscription at:

https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed January 9, 2023.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-233364
Guideline Name	State Mandate Reference Document
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	3/6/2025

1 . Criteria

Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Arkansas			
California			
Connecticut			
Georgia			
Indiana			
Kentucky			
Maryland			
New York			

West Virginia			
State			
Mandate			
Colorado			
Delaware			
Iowa			
Illinois			
Louisiana			
Maine			
Minnesota			
New Mexico			
North Dakota			
Oklahoma			
Pennsylvania			
South Dakota			
Texas			
Virginia			
Wisconsin			
Florida			
Massachusetts			

Approval Criteria

1 - The following mandates apply to Illinois:

1.1 Effective 1/1/2018, step therapy requirements are deemed met if the provider submits medical records confirming the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

1.2 Effective 1/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-

approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

1.3 Effective 6/9/2023, all clinical criteria are deemed met for the requested therapy when the medication is being used for a diagnosis of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) or pediatric acute onset neuropsychiatric syndrome (PANS).

OR

2 - The following mandates apply to Iowa:

2.1 Effective 1/1/2018, any clinical criteria component involving a trial/failure requirement are deemed met if supporting rationale and documentation demonstrate any of the following circumstances apply:

2.1.1 The prescription drug required under the tried/failed protocol is contraindicated pursuant to the drug manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:

Cause an adverse reaction to a patient.

Decrease the ability of a patient to achieve or maintain reasonable functional ability in performing daily activities.

Cause physical or mental harm to a patient.

OR

2.1.2 The prescription drug required under the tried/failed protocol is expected to be ineffective based on the known clinical characteristics of the patient, such as the patient's adherence to or compliance with the patient's individual plan of care, and any of the following:

The known characteristics of the prescription drug regimen as described in peer-reviewed literature or in the manufacturer's prescribing information for the drug.

The health care professional's medical judgment based on clinical practice guidelines or peer-reviewed journals.

The patient's documented experience with the prescription drug regimen.

OR

2.1.3 The patient has had a trial of a therapeutically equivalent dose of the prescription drug under the tried/failed protocol while under the patient's current or previous health benefit plan for a period of time to allow for a positive treatment outcome, and such prescription drug was discontinued by the patient's health care professional due to lack of effectiveness.

OR

2.1.4 The patient is currently receiving a positive therapeutic outcome on a prescription drug selected by the patient's health care professional for the medical condition under consideration while under the patient's current or previous health benefit plan. Note: Bypass protocols may be applied to all applicable medications except a generic equivalent or interchangeable biological product. The use of a pharmaceutical sample for the sole purpose of meeting the requirements for a tried/failed exception may not count as sufficient experience with the requested medication to be considered stable on the medication.

OR

2.2 Effective 1/1/2025, all clinical criteria are deemed met for a covered prescription drug for any patient who is stable on such drug as determined by the prescribing health care professional, if all of the following apply:

The prescription drug was previously approved by the health carrier for coverage for the patient.

The patient's prescribing health care professional has prescribed the drug for the patient's medical condition within the previous six months.

The patient continues to be an enrollee for the health benefit plan

OR

3 - The following applies to Minnesota:

3.1 Effective 1/1/2020, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network

Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer

OR

3.2 Effective 1/1/2020, all clinical criteria are deemed met for the requested therapy when the medication is being used for a diagnosis of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) or pediatric acute onset neuropsychiatric syndrome (PANS)

OR

3.3 Effective 1/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if at least one of the following apply:

3.3.1 The provider submits documentation that the required prescription drug is contraindicated pursuant to the pharmaceutical manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:

Cause an adverse reaction to the patient

Decrease the ability of the patient to achieve or maintain reasonable functional ability in performing daily activities

Cause physical or mental harm to the patient

OR

3.3.2 The patient has had a trial of the required prescription drug covered by their current or previous health plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, was adherent for a period of time sufficient to allow for a positive treatment outcome, and the prescription drug was discontinued due to lack of effectiveness or an adverse event.

OR

3.3.3 The provider submits documentation that the patient is currently receiving a positive therapeutic outcome on a prescription drug if, while on their current health plan or the immediately preceding health plan, the patient received coverage for the prescription drug and that the change in the required prescription drug is expected to be ineffective or cause

harm to the patient based on the known characteristics of the specific patient and the known characteristics of the required prescription drug. Note: Bypass protocols may be applied to all applicable medications except a generic equivalent drug or a biosimilar. Pharmaceutical samples cannot be used for the primary purpose of meeting the requirements for an exception. Biosimilar (United States Code, chapter 42, section 262(i)(2): The biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product

OR

3.4 Effective 7/1/2018, all clinical criteria and review types other than quantity limit are deemed met for an antipsychotic drug prescribed to treat emotional disturbance or mental illness, when the health care provider indicates orally or in writing that the prescription must be dispensed as communicated to provide maximum medical benefit to the patient and certifies in writing that they have considered all equivalent drugs in the formulary and have determined that the drug prescribed will best treat the patient's condition. Note: If a medication is being approved using the Minnesota Antipsychotic Bypass Protocol, the case should be approved for one (1) year, unless a longer duration is specified in a drug-specific guideline. Emotional Disturbance: An organic disorder of the brain or a clinically significant disorder of thought, mood, perception, orientation, memory, or behavior that is detailed in a diagnostic codes list published by the commissioner and seriously limits a child's capacity to function in primary aspects of daily living such as personal relations, living arrangements, work, school, and recreation. Emotional Disturbance is a generic term and is intended to reflect all categories of disorder described in the clinical code list published by the commissioner as "usually first evident in childhood or adolescence." Mental Illness: An organic disorder of the brain or a clinically significant disorder of thought, mood, perception, orientation, memory, or behavior that is detailed in a diagnostic codes list published by the commissioner, and that seriously limits a person's capacity to function in primary aspects of daily living such as personal relations, living arrangements, work, and recreation

OR

4 - For Wisconsin, (effective 11/1/2019), any clinical criteria component involving a trial/failure requirement are deemed met when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Any clinical criteria component involving a trial/failure requirement are also deemed met if the provider submits medical records confirming that the patient is

currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

2 . Background

Benefit/Coverage/Program Information
Background: This document serves as a reference for changes requested to pharmacy utilization management programs based on state mandates. This includes but is not limited to step therapy, prior authorization regulations, supply limits, first line trial duration limitations, and pain therapy/end of life regulations. **Additional Clinical Rules:** Applicable clinical programs will apply.

3 . Revision History

Date	Notes
3/6/2025	Updated state mandate for Iowa.

Prior Authorization Guideline

Guideline ID	GL-228544
Guideline Name	Statins
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Altoprev (lovastatin extended-release)
Prevention of coronary heart disease A) Indicated in patients without symptomatic coronary heart disease (CHD), but at high risk, to reduce the risk of myocardial infarction, unstable angina, and coronary revascularization procedures. B) Indicated to slow the progression of coronary atherosclerosis in patients with coronary heart disease as part of a treatment strategy to lower Total-C and LDL-C to target levels. Limitations of use: Altoprev has not been studied in Fredrickson Types I, III, and V. **Hyperlipidemia** Indicated as an adjunct to diet for the reduction of elevated Total-C, LDL-C, Apo B, and TG, and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and non-familial) and mixed dyslipidemia (Fredrickson types IIa and IIb). Limitations of use: Altoprev has not been studied in Fredrickson Types I, III, and V.
Drug Name: Lipitor (atorvastatin)
Prevention of cardiovascular disease A) Indicated in adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, to reduce the risk of myocardial infarction, risk of stroke, and risk for revascularization

procedures and angina. B) Indicated in adult patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, to reduce the risk of myocardial infarction and stroke. C) Indicated in adult patients with clinically evident coronary heart disease to reduce the risk of non-fatal myocardial infarction, fatal and non-fatal stroke, revascularization procedures, hospitalization for chronic heart failure (CHF), and angina.

Hyperlipidemia Indicated as 1) An adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in: a) Adults with primary hyperlipidemia and b) Adult and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH). 2) As an adjunct to other LDL-C lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH). 3) As an adjunct to diet for the treatment of adults with: a) primary dysbetalipoproteinemia and b) hypertriglyceridemia.

Drug Name: Zypitamag (pitavastatin magnesium)

Primary hyperlipidemia and mixed dyslipidemia Indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hyperlipidemia or mixed dyslipidemia. Limitations of use: The effect of Zypitamag on cardiovascular morbidity and mortality has not been determined.

Drug Name: Livalo (pitavastatin calcium)

Primary hyperlipidemia and mixed dyslipidemia Indicated as an adjunctive therapy to diet in: A) Adults with primary hyperlipidemia and B) Adults and pediatric patients aged 18 years and older with heteroygous familial hypercholesterolemia (HeFH).

Drug Name: Flolipid (simvastatin)

Reductions in risk of CHD mortality and cardiovascular events Indicated in patients at high risk of coronary events because of existing coronary heart disease, diabetes, peripheral vessel disease, history of stroke or other cerebrovascular disease to reduce the risk of total mortality by reducing CHD deaths, non-fatal myocardial infarction and stroke, and reduce the need for coronary and non-coronary revascularization procedures. Limitations of use: Flolipid has not been studied in conditions where the major abnormality is elevation of chylomicrons (i.e., hyperlipidemia Fredrickson types I and V).

Hyperlipidemia Indicated to reduce elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), and triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hyperlipidemia (Fredrickson type IIa, heterozygous familial and nonfamilial) or mixed dyslipidemia (Fredrickson type IIb); to reduce elevated TG in patients with hypertriglyceridemia (Fredrickson type IV hyperlipidemia); to reduce elevated TG and VLDL-C in patients with primary dysbetalipoproteinemia (Fredrickson type III hyperlipidemia); and to reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH) as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable. Limitations of use: Flolipid has not been studied in conditions where the major abnormality is

elevation of chylomicrons (i.e., hyperlipidemia Fredrickson types I and V).

Adolescent patients with heterozygous familial hypercholesterolemia (HeFH) Indicated as an adjunct to diet to reduce total-C, LDL-C, and Apo B levels in adolescent boys and girls who are at least one year post-menarche, 10-17 years of age, with HeFH, if after an adequate trial of diet therapy the following findings are present: (1) LDL cholesterol remains greater than or equal to 190 mg/dL; or (2) LDL cholesterol remains greater than or equal to 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors are present in the adolescent patient. The minimum goal of treatment in pediatric and adolescent patients is to achieve a mean LDL-C less than 130 mg/dL. The optimal age at which to initiate lipid-lowering therapy to decrease the risk of symptomatic adulthood CAD has not been determined. Limitations of use: Flolipid has not been studied in conditions where the major abnormality is elevation of chylomicrons (i.e., hyperlipidemia Fredrickson types I and V).

Drug Name: Ezallor (rosuvastatin)

Homozygous familial hypercholesterolemia (HoFH) Indicated as an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 7 years and older with homozygous familial hypercholesterolemia (HoFH).

Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia) Indicated as an adjunct to diet for the treatment of adult patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia) or Hypertriglyceridemia.

Heterozygous Familial Hypercholesterolemia Indicated as an adjunct to diet to: A) reduce LDL-C in adults with primary hyperlipidemia, B) Reduce low-density lipoprotein (LDL-C) and slow the progression of atherosclerosis in adults, or C) Reduce LDL-C in adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).

Prevention of Cardiovascular disease Indicated to reduce the risk of stroke, myocardial infarction, and arterial revascularization procedures in adults without established coronary heart disease who are at increased risk of cardiovascular (CV) disease based on age, hsCRP ≥2 mg/L, and at least one additional CV risk factor.

Drug Name: Lescol XL (fluvastatin sodium) extended-release

Hypercholesterolemia Indicated as an adjunct to reduce LDL-C in adults and pediatric patients 10 years of age and older with heterozygous familial hypercholesterolemia (HeFH) who require 80 mg of fluvastatin daily.

Primary hyperlipidemia Indicated as an adjunct to diet to reduce LDL-C in adults with primary hyperlidpidemia.

Secondary Prevention of Cardiovascular Disease Indicated in patients with clinically evident Coronary Heart Disease (CHD) to reduce the risk of undergoing coronary revascularization procedures and slow the progression of coronary atherosclerosis.

Drug Name: Zocor (simvastatin) film coated
Diagnosis A) Indicated to reduce the risk of total mortality by reducing risk of coronary heart disease death, non-fatal myocardial infarction and stroke, and the need for coronary and noncoronary revascularization procedures in adults with established coronary heart disease, cerebrovascular disease, peripheral vascular disease, and/or diabetes, who are at high risk of coronary heart disease events. B) As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C): In adults with primary hyperlipidemia, In adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH). C) Indicated as an adjunct to other LDL-C-lowering therapies to reduce LDL-C in adults with homozygous familial hypercholesterolemia (HoFH). D) Indicated as an adjunct to diet for the treatment of adults with Primary dysbetalipoproteinemia, Hypertriglyceridemia.

2 . Criteria

Product Name:Altoprev*, Ezallor*, Flolipid*, Brand Lescol XL*, Livalo*, Brand Lipitor*, Brand Zocor*	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ALTOPREV	LOVASTATIN TAB SR 24HR 20 MG	39400050007520	Brand
ALTOPREV	LOVASTATIN TAB SR 24HR 40 MG	39400050007530	Brand
ALTOPREV	LOVASTATIN TAB SR 24HR 60 MG	39400050007540	Brand
LIPITOR	ATORVASTATIN CALCIUM TAB 10 MG (BASE EQUIVALENT)	39400010100310	Brand
LIPITOR	ATORVASTATIN CALCIUM TAB 20 MG (BASE EQUIVALENT)	39400010100320	Brand
LIPITOR	ATORVASTATIN CALCIUM TAB 40 MG (BASE EQUIVALENT)	39400010100330	Brand
LIPITOR	ATORVASTATIN CALCIUM TAB 80 MG (BASE EQUIVALENT)	39400010100350	Brand
FLOLIPID	SIMVASTATIN SUSP 20 MG/5ML (4 MG/ML)	39400075001810	Brand
FLOLIPID	SIMVASTATIN SUSP 40 MG/5ML (8 MG/ML)	39400075001820	Brand
EZALLOR SPRINKLE	ROSUVASTATIN CALCIUM SPRINKLE CAP 5 MG (BASE EQUIVALENT)	39400060106805	Brand
EZALLOR SPRINKLE	ROSUVASTATIN CALCIUM SPRINKLE CAP 10 MG (BASE EQUIVALENT)	39400060106810	Brand

EZALLOR SPRINKLE	ROSUVASTATIN CALCIUM SPRINKLE CAP 20 MG (BASE EQUIVALENT)	39400060106820	Brand
EZALLOR SPRINKLE	ROSUVASTATIN CALCIUM SPRINKLE CAP 40 MG (BASE EQUIVALENT)	39400060106840	Brand
LESCOL XL	FLUVASTATIN SODIUM TAB ER 24 HR 80 MG (BASE EQUIVALENT)	39400030107530	Brand
ZOCOR	SIMVASTATIN TAB 10 MG	39400075000320	Brand
ZOCOR	SIMVASTATIN TAB 20 MG	39400075000330	Brand
ZOCOR	SIMVASTATIN TAB 40 MG	39400075000340	Brand
ZOCOR	SIMVASTATIN TAB 80 MG	39400075000360	Brand
LIVALO	PITAVASTATIN CALCIUM TAB 1 MG	39400058100321	Brand
LIVALO	PITAVASTATIN CALCIUM TAB 2 MG	39400058100331	Brand
LIVALO	PITAVASTATIN CALCIUM TAB 4 MG	39400058100341	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) or intolerance to one of the following generics:

atorvastatin

fluvastatin

fluvastatin ER

lovastatin

pravastatin

rosuvastatin

simvastatin

Notes	*Step Therapy may not apply depending on the plan.

Product Name:Zypitamag*	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ZYPITAMAG	PITAVASTATIN MAGNESIUM TAB 2 MG (BASE EQUIV)	39400058300330	Brand
ZYPITAMAG	PITAVASTATIN MAGNESIUM TAB 4 MG (BASE EQUIV)	39400058300340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) or intolerance to one of the following generics:

atorvastatin

fluvastatin

fluvastatin ER

lovastatin

pravastatin

rosuvastatin

simvastatin

AND

3 - Trial and failure (of a minimum 30-day supply), or intolerance to Livalo

Notes	*Step Therapy may not apply depending on the plan.

3 . References

Altoprev Prescribing Information. Covis Pharma. Zug, Switzerland. September 2020.

Lipitor Prescribing Information. Pfizer Inc. New York, NY. December 2022.

Livalo Prescribing Information. Kowa Pharmaceuticals America, Inc. Montgomery, AL. November 2022.

Zypitamag Prescribing Information. Zydus Pharmaceuticals, Inc. Pennington, NJ. September 2020.

Flolipid Prescribing Information. Salerno Pharmaceuticals LP. Brooksville, FL. September 2020.

Ezallor Prescribing Information. Sun Pharmaceutical Industries, Ltd. August 2023.

Lescol XL Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. November 2023.

Prior Authorization Guideline

Guideline ID	GL-228983
Guideline Name	Stelara (ustekinumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Stelara SC (ustekinumab)
Plaque Psoriasis (PsO) Indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of patients 6 years or older with active psoriatic arthritis. **Crohn's Disease (CD)** Indicated for the treatment of adult patients with moderately to severely active Crohn's disease. **Ulcerative Colitis (UC)** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.
Drug Name: Stelara IV (ustekinumab)
Crohn's Disease (CD) Indicated for the treatment of adult patients with moderately to severely active Crohn's disease.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

2 . Criteria

Product Name:Stelara SC 45 mg/0.5 mL	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

Greater than or equal to 3% body surface area involvement

Severe scalp psoriasis

Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

5 - Prescribed by or in consultation with a dermatologist

Product Name:Stelara SC 90 mg/1 mL	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

Greater than or equal to 3% body surface area involvement

Severe scalp psoriasis

Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient's weight is greater than 100 kg (220 lbs)

AND

4 - Patient is 6 years of age or older

AND

5 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

6 - Prescribed by or in consultation with a dermatologist

Product Name:Stelara SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Stelara SC 45 mg/0.5 mL	
Diagnosis	Psoriatic arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

Product Name:Stelara SC 90 mg/1 mL	
Diagnosis	Psoriatic arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Diagnosis of co-existent moderate to severe psoriasis [1, 4]

AND

4 - Patient's weight is greater than 100 kg (220 lbs)

AND

5 - Patient is 6 years of age or older

AND

6 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

Diagnosis	Psoriatic arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

Product Name:Stelara IV	
Diagnosis	Crohn's Disease
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INFUSION)	52504070002020	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [5, 6]:

Frequent diarrhea and abdominal pain

At least 10% weight loss

Complications such as obstruction, fever, abdominal mass

Abnormal lab values (e.g., C-reactive protein [CRP])

CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [5, 6]:

6-mercaptopurine

azathioprine

corticosteroids (e.g., prednisone)

methotrexate

AND

4 - Stelara is to be administered as an intravenous induction dose

AND

5 - Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's disease:

260 mg for patients weighing 55 kg or less

390 mg for patients weighing more than 55 kg to 85 kg

520 mg for patients weighing more than 85 kg

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name:Stelara SC	
Diagnosis	Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Will be used as a maintenance dose following the intravenous induction dose

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name:Stelara IV

Diagnosis	Ulcerative Colitis
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INFUSION)	52504070002020	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, ESR, CRP)

Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [7, 8]:

Corticosteroid (e.g., prednisone)

6-mercaptopurine

Azathioprine

Aminosalicylates (e.g., mesalamine, olsalazine, sulfasalazine)

AND

4 - Stelara is to be administered as an intravenous induction dose

AND

5 - Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for ulcerative colitis:

260 mg for patients weighing 55 kg or less

390 mg for patients weighing more than 55 kg to 85 kg

520 mg for patients weighing more than 85 kg

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name:Stelara SC	
Diagnosis	Ulcerative Colitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Will be used as a maintenance dose following the intravenous induction dose

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name:Stelara SC	
Diagnosis	Crohn's Disease and Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5-8]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

3 . References

Stelara prescribing information. Janssen Biotech, Inc. Horsham PA. March 2024.

Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.

Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.

Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.

Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228986
Guideline Name	Stivarga (regorafenib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Stivarga (regorafenib)
Metastatic Colorectal Cancer (mCRC) Indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild- type, an anti-EGFR therapy. **Gastrointestinal Stromal Tumor (GIST)** Indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate. **Hepatocellular Carcinoma (HCC)** Indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

2 . Criteria

Product Name:Stivarga	
Diagnosis	Metastatic Colorectal Cancer (mCRC) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STIVARGA	REGORAFENIB TAB 40 MG	21533050000320	Brand

Approval Criteria

1 - Diagnosis of metastatic colorectal cancer (mCRC)

Product Name:Stivarga	
Diagnosis	Gastrointestinal Stromal Tumor (GIST) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STIVARGA	REGORAFENIB TAB 40 MG	21533050000320	Brand

Approval Criteria

1 - Diagnosis of Gastrointestinal Stromal Tumor (GIST)

AND

2 - Disease is one of the following:

Locally advanced

Unresectable

Metastatic

Product Name:Stivarga	
Diagnosis	Hepatocellular Carcinoma (HCC) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STIVARGA	REGORAFENIB TAB 40 MG	21533050000320	Brand

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma (HCC)

Product Name:Stivarga	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STIVARGA	REGORAFENIB TAB 40 MG	21533050000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Stivarga Prescribing Information. Bayer HealthCare Pharmaceuticals Inc., December 2020.

The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 19, 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233397
Guideline Name	Sublingual Allergen Immunotherapy Products (Grastek, Odactra, Oralair, Ragwitek)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	5/21/2014
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Grastek (Timothy Grass Pollen Allergen Extract)
Allergic Rhinitis Indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Grastek is approved for use in persons 5 through 65 years of age. Grastek is not indicated for the immediate relief of allergic symptoms.
Drug Name: Odactra (House Dust Mite [Dermatophagoides farinae and Dermatophagoides pteronyssinus] Allergen Extract)
Allergic Rhinitis Indicated as immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or by positive skin testing to licensed house dust mite allergen extracts. Odactra is

approved for use in persons 12 through 65 years of age. Odactra is not indicated for the immediate relief of allergic symptoms.
Drug Name: Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract)
Allergic Rhinitis Indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product. Oralair is approved for use in persons 5 through 65 years of age. Oralair is not indicated for the immediate relief of allergy symptoms.
Drug Name: Ragwitek (Short Ragweed Pollen Allergen Extract)
Allergic Rhinitis Indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. Ragwitek is approved for use in persons 5 through 65 years of age. Ragwitek is not indicated for the immediate relief of allergic symptoms.

2 . Criteria

Product Name:Grastek	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GRASTEK	TIMOTHY GRASS POLLEN ALLERGEN EXT TAB SL 2800 BAU	20100048000740	Brand

Approval Criteria

1 - Diagnosis of grass pollen-induced allergic rhinitis

AND

2 - Patient has a positive skin test or in vitro test for pollen-specific IgE antibodies to Timothy Grass or cross-reactive grass pollens

AND

3 - Treatment will be initiated 3 months before the expected onset of the grass pollen season

AND

4 - Patient is 5 to 65 years of age

AND

5 - Trial and failure, contraindication, or intolerance to both of the following:

An intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, flunisolide nasal spray)

An antihistamine (e.g., cetirizine, loratadine, azelastine nasal spray, olapatadine nasal spray)

AND

6 - Prescribed by or in consultation with an allergist or immunologist

Product Name:Odactra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ODACTRA	*DUST MITE MIXED EXT TAB SL 12 SQ-HDM***	20109902220740	Brand

Approval Criteria

1 - Diagnosis of house dust mite (HDM)-induced allergic rhinitis

AND

2 - Positive in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts

AND

3 - Patient is 12 to 65 years of age

AND

4 - Trial and failure, contraindication, or intolerance to both of the following:

An intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, flunisolide nasal spray)

An antihistamine (e.g., cetirizine, loratadine, azelastine nasal spray, olapatadine nasal spray)

AND

5 - Prescribed by or in consultation with an allergist or immunologist

Product Name:Oralair	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORALAIR CHILDREN/ADOLESCENTS STARTER PACK	*GRASS MIXED POLLEN EXT TAB SL 100 IR (INDEX OF REACTIVITY)*	20109905200720	Brand

ORALAIR	*GRASS MIXED POLLEN EXT TAB SL 300 IR (INDEX OF REACTIVITY)*	20109905200730	Brand
ORALAIR ADULT STARTER PACK	*GRASS MIXED POLLEN EXT TAB SL 300 IR (INDEX OF REACTIVITY)*	20109905200730	Brand

Approval Criteria

1 - Diagnosis of grass pollen-induced allergic rhinitis

AND

2 - Patient has a positive skin test or in vitro test for pollen-specific IgE antibodies to any of the five grass species including sweet vernal, orchard, perennial rye, timothy or kentucky blue grass mixed pollens

AND

3 - Treatment will be initiated 4 months before the expected onset of the grass pollen season

AND

4 - Patient is 5 to 65 years of age

AND

5 - Trial and failure, contraindication, or intolerance to both of the following:

An intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, flunisolide nasal spray)

An antihistamine (e.g., cetirizine, loratadine, azelastine nasal spray, olapatadine nasal spray)

AND

6 - Prescribed by or in consultation with an allergist or immunologist

Notes	ORALAIR Child Starter Packs/Sample Kits will only be approved for c hildren less than 18 years of age

Product Name:Ragwitek	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RAGWITEK	SHORT RAGWEED POLLEN ALLERGEN EXTRACT TAB SL 12 AMB A 1-U	20100060200720	Brand

Approval Criteria

1 - Diagnosis of short ragweed pollen-induced allergic rhinitis

AND

2 - Patient has a positive skin test or in vitro test for pollen-specific IgE antibodies to short ragweed pollen

AND

3 - Treatment will be initiated 3 months before the expected onset of the ragweed pollen season

AND

4 - Patient is 5 to 65 years of age

AND

5 - Trial and failure, contraindication, or intolerance both of the following:

An intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, flunisolide nasal spray)

An antihistamine (e.g., cetirizine, loratadine, azelastine nasal spray, olapatadine nasal spray)

AND

6 - Prescribed by or in consultation with an allergist or immunologist

Product Name:Grastek, Odactra, Oralair, Ragwitek	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GRASTEK	TIMOTHY GRASS POLLEN ALLERGEN EXT TAB SL 2800 BAU	20100048000740	Brand
RAGWITEK	SHORT RAGWEED POLLEN ALLERGEN EXTRACT TAB SL 12 AMB A 1-U	20100060200720	Brand
ORALAIR CHILDREN/ADOLESCENTS STARTER PACK	*GRASS MIXED POLLEN EXT TAB SL 100 IR (INDEX OF REACTIVITY)*	20109905200720	Brand
ORALAIR	*GRASS MIXED POLLEN EXT TAB SL 300 IR (INDEX OF REACTIVITY)*	20109905200730	Brand
ORALAIR ADULT STARTER PACK	*GRASS MIXED POLLEN EXT TAB SL 300 IR (INDEX OF REACTIVITY)*	20109905200730	Brand
ODACTRA	*DUST MITE MIXED EXT TAB SL 12 SQ-HDM***	20109902220740	Brand

Approval Criteria

1 - One of the following:

1.1 Patient has experienced improvement in the symptoms of their allergic rhinitis

OR

1.2 Patient has experienced a decrease in the number of medications needed to control allergy symptoms

3 . References

Grastek Prescribing Information. Catalent Pharma Solutions Limited. Swindon, UK. August 2022.

Oralair Prescribing Information. GREER Laboratories, Inc. Lenoir, NC. October 2024.

Ragwitek Prescribing Information. Catalent Pharma Solutions Limited. Swindon, UK. September 2022.

Odactra Prescribing Information. Catalent Pharma Solutions Limited. Swindon, UK. October 2023.

Dykewicz MS, Wallace DV, Amrol DJ, et al. Rhinitis 2020: a practice parameter update. J Allergy Clin Immunol. 2020;146(4):721-767. doi:10.1016/j.jaci.2020.07.007.

4 . Revision History

Date	Notes
3/14/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-233249
Guideline Name	Sucraid (sacrosidase) Oral Solution
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	12/14/2022
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Sucraid (sacrosidase) Oral Solution
Congenital Sucrase-Isomaltase Deficiency (CSID) Indicated for the treatment of sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID), in adult and pediatric patients 5 months of age and older.

2 . Criteria

Product Name:Sucraid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUCRAID	SACROSIDASE SOLN 8500 UNIT/ML	51200060002030	Brand

Approval Criteria

1 - Diagnosis of sucrase deficiency (which is part of congenital sucrose-isomaltase deficiency [CSID])

AND

2 - Disease is confirmed by ONE of the following: [1, 2]

Disaccharidase assay via a small bowel biopsy

Carbon -13 sucrose breath test

Molecular genetic testing confirms mutation in the SI gene

Stool pH less than 6, an increase in breath hydrogen of greater than 10 parts-per-million (ppm) when challenged with sucrose after fasting and a negative lactose breath test

AND

3 - Patient is 5 months of age or older.

AND

4 - Prescribed by or in consultation with ONE of the following:

Gastroenterologist

Geneticist

Product Name:Sucraid

Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUCRAID	SACROSIDASE SOLN 8500 UNIT/ML	51200060002030	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decrease in symptoms of abdominal pain, cramps, bloating or gas; decrease in number and frequency of stools per day)

3 . References

Sucraid Prescribing Information. QOL Medical, LLC. Vero Beach, FL. August 2024.

Congenital Sucrase-Isomaltase Deficiency (CSID). International Foundation for Gastrointestinal Disorders. Available at https://iffgd.org/gi-disorders/congenital-sucrase-isomaltase-deficiency-csid/. Accessed October 24, 2022.

Smith, H., Romero, B., et al. The patient journey to diagnosis and treatment of congenital sucrase-isomaltase deficiency. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8298246/. Accessed October 24, 2022.

Chey, W., Cash, B., et al. Congenital Sucrase-Isomaltase Deficiency: What, When, and How? Gastroenterology and Hepatology. October 2020. Available at https://www.gastroenterologyandhepatology.net/files/2020/10/gh1020sup5-1.pdf. Accessed October 24, 2022.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Sunlenca (lenacapavir sodium)

Prior Authorization Guideline

Guideline ID	GL-228546
Guideline Name	Sunlenca (lenacapavir sodium)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sunlenca (lenacapavir sodium)
Multidrug Resistant HIV-1 Infection Indicated in combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

2 . Criteria

Product Name:Sunlenca	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUNLENCA	LENACAPAVIR SODIUM TAB THERAPY PACK 4 X 300 MG	1210155520B720	Brand
SUNLENCA	LENACAPAVIR SODIUM TAB THERAPY PACK 5 X 300 MG	1210155520B725	Brand
SUNLENCA	LENACAPAVIR SODIUM SUBCUTANEOUS SOLN 463.5 MG/1.5ML	12101555202030	Brand

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Both of the following:

1.2.1 Patient is heavily treatment-experienced with multidrug resistance as confirmed by a resistance assay

AND

1.2.2 Patient is failing their current antiretroviral regimen due to one of the following:

Resistance

Intolerance

Safety considerations

AND

1.3 Patient is currently taking, or will be prescribed, an active and optimized background antiretroviral therapy regimen

AND

1.4 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - For continuation of prior therapy

3 . References

Sunlenca Prescribing Information. Gilead Sciences, Inc. Foster City, CA. September 2023.

Prior Authorization Guideline

Guideline ID	GL-228988
Guideline Name	Sunosi (solriamfetol)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sunosi (solriamfetol)
Narcolepsy Indicated to improve wakefulness in adults patients with excessive daytime sleepiness associated with narcolepsy. **Obstructive sleep apnea (OSA)** Indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with obstructive sleep apnea (OSA). Limitations of use: Sunosi is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating Sunosi for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi. Sunosi is not a substitute for these modalities.

2 . Criteria

Product Name:Sunosi	
Diagnosis	Narcolepsy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUNOSI	SOLRIAMFETOL HCL TAB 75 MG (BASE EQUIV)	61370070200320	Brand
SUNOSI	SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV)	61370070200340	Brand

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [A, B]

AND

2 - BOTH of the following;

2.1 Trial and failure, contraindication, or intolerance to ONE of the following:

generic modafinil

generic armodafinil

AND

2.2 ONE of the following:

2.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

2.2.2 History of or potential for a substance use disorder

Product Name:Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUNOSI	SOLRIAMFETOL HCL TAB 75 MG (BASE EQUIV)	61370070200320	Brand
SUNOSI	SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV)	61370070200340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

Product Name:Sunosi	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUNOSI	SOLRIAMFETOL HCL TAB 75 MG (BASE EQUIV)	61370070200320	Brand
SUNOSI	SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV)	61370070200340	Brand

Approval Criteria

1 - Diagnosis of obstructive sleep apnea defined by one of the following: [4]

1.1 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [C]

OR

1.2 Both of the following:

1.2.1 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [C]

AND

1.2.2 One of the following signs/symptoms are present:

Daytime sleepiness

Nonrestorative sleep

Fatigue

Insomnia

Waking up with breath holding, gasping, or choking

Habitual snoring noted by a bed partner or other observer

Observed apnea

AND

2 - Both of the following:

2.1 Standard treatment(s) for the underlying obstruction (e.g., with continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

3 - Trial and failure, contraindication or intolerance to ONE of the following:

generic modafinil

generic armodafinil

Product Name:Sunosi	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUNOSI	SOLRIAMFETOL HCL TAB 75 MG (BASE EQUIV)	61370070200320	Brand
SUNOSI	SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV)	61370070200340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

AND

2 - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP)

3 . Endnotes

International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 1 (narcolepsy with cataplexy) require: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) The presence of one or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT; or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than or equal to 110 pg/mL or less than

one-third of mean values obtained in normal subjects with the same standardized assay) [2,3].

International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 2 (narcolepsy without cataplexy) include: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) Cataplexy is absent. 3) CSF hypocretin-1 levels, if measured, is either greater than 100 pg/mL or greater than one-third of mean values obtained in normal subjects with the same standardized assay. 4) A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT. 5) Hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal [2,3].

Examples of obstructive respiratory events include: obstructive and mixed apneas, hypopneas, or respiratory effort related arousals (RERA) [2].

4 . References

Sunosi Prescribing Information. Jazz Pharmaceuticals, Inc. Palo Alto, CA. October 2021.

Sateia MJ. International classification of sleep disorders - third edition: highlights and modifications. CHEST. 2014 Nov;146(5):1387-1394.

UpToDate. Clinical features and diagnosis of narcolepsy. Available by subscription at: https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-narcolepsy-in-adults?search=Clinical%20features%20and%20diagnosis%20of%20narcolepsy&source=search_result&selectedTitle=1~116&usage_type=default&display_rank=1. Accessed March 30, 2020.

UpToDate. Clinical presentation and diagnosis of obstructive sleep apnea in adults. Available by subscription at: https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-obstructive-sleep-apnea-in-adults?search=obstructive%20sleep%20apnea&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4. Accessed March 30, 2020.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228990
Guideline Name	Sutent (sunitinib) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sutent (sunitinib)
Gastrointestinal stromal tumor (GIST) Indicated for the treatment of adult patients with gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate. **Advanced pancreatic neuroendocrine tumors (pNET)** Indicated for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in adult patients with unresectable locally advanced or metastatic disease. **Advanced renal cell carcinoma** Indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC). **Adjuvant treatment of renal cell carcinoma** Indicated for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy.

2 . Criteria

Product Name:Brand Sutent, Generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - History of disease progression, contraindication, or intolerance to Gleevec (imatinib)

AND

3 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name:Brand Sutent, Generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name:Brand Sutent	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming history of disease progression, contraindication, or intolerance to Gleevec (imatinib)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

Product Name:Brand Sutent, Generic sunitinib	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand

SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET)

AND

2 - One of the following:

unresectable locally advanced disease

metastatic disease

AND

3 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name:Brand Sutent, Generic sunitinib	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand

SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name:Brand Sutent	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand

Approval Criteria

1 - Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET)

AND

2 - One of the following:

unresectable locally advanced disease

metastatic disease

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

Product Name:Brand Sutent, Generic sunitinib	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Diagnosis of advanced/metastatic renal cell carcinoma

AND

2 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name:Brand Sutent, Generic sunitinib	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name:Brand Sutent	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand

Approval Criteria

1 - Diagnosis of advanced/metastatic renal cell carcinoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

Product Name:Brand Sutent, Generic sunitinib	
Diagnosis	Adjuvant Treatment of Renal Cell Carcinoma
Approval Length	12 Months [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand

SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - Used as adjuvant therapy

AND

3 - Patient is at high risk of recurrent RCC following nephrectomy

AND

4 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name:Brand Sutent	
Diagnosis	Adjuvant Treatment of Renal Cell Carcinoma
Approval Length	12 Months [A]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - Used as adjuvant therapy

AND

3 - Patient is at high risk of recurrent RCC following nephrectomy

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

3 . Endnotes

The recommended dose of Sutent for the adjuvant treatment of RCC is 50mg taken orally once daily, on a schedule of 4 weeks on treatment followed by 2 weeks off (Schedule 4/2), for nine 6-week cycles (approximately 1 year). [1]

4 . References

Sutent Prescribing Information. Pfizer Labs. New York, NY. August 2021.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228721
Guideline Name	Sylvant (siltuximab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sylvant (siltuximab)
Multicentric Castleman's Disease Indicated for the treatment of patients with multicentric Castleman’s disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative. Limitation of use: Sylvant was not studied in patients with MCD who are HIV positive or HHV-8 positive because Sylvant did not bind to virally produced IL-6 in a nonclinical study.

2 . Criteria

Product Name:Sylvant	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYLVANT	SILTUXIMAB FOR IV INFUSION 100 MG	99473080002120	Brand
SYLVANT	SILTUXIMAB FOR IV INFUSION 400 MG	99473080002140	Brand

Approval Criteria

1 - Diagnosis of multicentric Castleman's disease (MCD)

AND

2 - Patient is human immunodeficiency virus (HIV) negative

AND

3 - Patient is human herpesvirus-8 (HHV-8) negative

Product Name:Sylvant	
Approval Length	6 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYLVANT	SILTUXIMAB FOR IV INFUSION 100 MG	99473080002120	Brand
SYLVANT	SILTUXIMAB FOR IV INFUSION 400 MG	99473080002140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Patient is human immunodeficiency virus (HIV) negative

AND

3 - Patient is human herpesvirus-8 (HHV-8) negative

3 . Endnotes

Patients should be evaluated for response to the drug every 3-6 months. A length of authorization of 6 months would be reasonable. [2]

4 . References

Sylvant Prescribing Information. Janssen Biotech, Inc. Horsham PA. April 2022.

Per clinical consult with hematologist/oncologist, June 5, 2014.

Symdeko (tezacaftor/ivacaftor)

Prior Authorization Guideline

Guideline ID	GL-228548
Guideline Name	Symdeko (tezacaftor/ivacaftor)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Symdeko (tezacaftor/ivacaftor)
Cystic Fibrosis (CF) Indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

2 . Criteria

Product Name:Symdeko	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYMDEKO	TEZACAFTOR-IVACAFTOR 100-150 MG & IVACAFTOR 150 MG TAB TBPK	4530990280B720	Brand
SYMDEKO	TEZACAFTOR-IVACAFTOR 50-75 MG & IVACAFTOR 75 MG TAB TBPK	4530990280B710	Brand

Approval Criteria

1 - Patient is 6 years of age or older

AND

2 - Diagnosis of cystic fibrosis (CF) [2,3]

AND

3 - One of the following:

3.1 Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

3.2 Patient has at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based in vitro data and/or clinical evidence* as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist Specialist affiliated with a CF care center

Notes	*Please consult Background section for table of CFTR gene mutations responsive to Symdeko.

Product Name:Symdeko	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYMDEKO	TEZACAFTOR-IVACAFTOR 100-150 MG & IVACAFTOR 150 MG TAB TBPK	4530990280B720	Brand
SYMDEKO	TEZACAFTOR-IVACAFTOR 50-75 MG & IVACAFTOR 75 MG TAB TBPK	4530990280B710	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations) [2,3]

3 . Background

Clinical Practice Guidelines
CFTR Gene Mutations that are Responsive to Symdeko [1] *Intent of table is to provide a quick reference; PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 1/29/24]
List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to Symdek

546insCTA	*E92K*	*G576A*	*L346P*	*R117G*	*S589N*
*711+3A→G **	*E116K*	*G576A;R668C †*	*L967S*	*R117H*	*S737F*
*2789+5G→A **	*E193K*	*G622D*	*L997F*	*R117L*	*S912L*
*3272-26A→G **	*E403D*	*G970D*	*L1324P*	*R117P*	*S945L **
*3849+10kbC→T **	*E588V*	*G1069R*	*L1335P*	*R170H*	*S977F **
A120T	*E822K*	*G1244E*	*L1480P*	*R258G*	*S1159F*
A234D	*E831X*	*G1249R*	*M152V*	*R334L*	*S1159P*
A349V	*F191V*	*G1349D*	*M265R*	*R334Q*	*S1251N*
*A455E **	*F311del*	*H939R*	*M952I*	*R347H **	*S1255P*
A554E	*F311L*	*H1054D*	*M952T*	*R347L*	*T338I*
A1006E	*F508C*	*H1375P*	*P5L*	*R347P*	*T1036N*
A1067T	*F508C;S1251N †*	*I148T*	*P67L **	*R352Q **	*T1053I*
D110E	*F508del ^*	*I175V*	*P205S*	*R352W*	*V201M*
*D110H **	*F575Y*	*I336K*	*Q98R*	*R553Q*	*V232D*
D192G	*F1016S*	*I601F*	*Q237E*	*R668C*	*V562I*
D443Y	*F1052V*	*I618T*	*Q237H*	*R751L*	*V754M*
D443Y;G576A;R668C †	*F1074L*	*I807M*	*Q359R*	*R792G*	*V1153E*
*D579G **	*F1099L*	*I980K*	*Q1291R*	*R933G*	*V1240G*
D614G	*G126D*	*I1027T*	*R31L*	*R1066H*	*V1293G*
D836Y	*G178E*	*I1139V*	*R74Q*	*R1070Q*	*W1282R*
D924N	*G178R*	*I1269N*	*R74W*	*R1070W **	*Y109N*
D979V	*G194R*	*I1366N*	*R74W;D1270N †*	*R1162L*	*Y161S*
*D1152H **	*G194V*	*K1060T*	*R74W;V201M †*	*R1283M*	*Y1014C*

D1270N	*G314E*	*L15P*	*R74W;V201M;D1270N* †	*R1283S*
E56K	*G551D*	*L206W* *	*R75Q*	*S549N*
E60K	*G551S*	*L320V*	*R117C* *	*S549R*

* Clinical data for these mutations in Clinical Studies.

^ A patient must have two copies of the *F508del* mutation or at least one copy of a responsive m

presented in Table 6 to be indicated.

† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations

these exist independent of the presence of mutations on the other allele.

4 . References

Symdeko Prescribing information. Vertex Pharmaceuticals Inc. Boston, MA. August 2023.

Cousar-Taylor J, Munch A, McKone E, et al. Tezacaftor-ivacaftor in patients with cystic fibrosis homozygous for phe508del. N Engl J Med. 2017; 1-11.

Rowe S, Daines C, Ringshausen F, et al. Tezacaftor-ivacaftor in residual-function heterozygotes with cystic fibrosis. N Engl J Med. 2017; 1-12.

Prior Authorization Guideline

Guideline ID	GL-228549
Guideline Name	Symlin (pramlintide acetate injection)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Symlin (pramlintide acetate)
Type 1 Diabetes Mellitus Indicated as an adjunctive treatment in patients with type 1 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy. **Type 2 Diabetes Mellitus** Indicated as an adjunctive treatment in patients with type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.

2 . Criteria

Product Name:Symlin	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYMLINPEN 60	PRAMLINTIDE ACETATE PEN-INJ 1500 MCG/1.5ML (1000 MCG/ML)	2715005010D220	Brand
SYMLINPEN 120	PRAMLINTIDE ACETATE PEN-INJ 2700 MCG/2.7ML (1000 MCG/ML)	2715005010D240	Brand

Approval Criteria

1 - One of the following diagnoses:

Type 1 diabetes

Type 2 diabetes

AND

2 - Patient has failed to achieve desired glucose control despite optimal insulin therapy

AND

3 - Patient is taking concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog)

Product Name:Symlin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYMLINPEN 60	PRAMLINTIDE ACETATE PEN-INJ 1500 MCG/1.5ML (1000 MCG/ML)	2715005010D220	Brand
SYMLINPEN 120	PRAMLINTIDE ACETATE PEN-INJ 2700 MCG/2.7ML (1000 MCG/ML)	2715005010D240	Brand

Approval Criteria

1 - Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline

AND

2 - Patient is receiving concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog)

3 . References

Symlin Prescribing Information. Amylin Pharmaceuticals, Inc. Wilmington, DE. December 2019.

Synagis (palivizumab)

Prior Authorization Guideline

Guideline ID	GL-228992
Guideline Name	Synagis (palivizumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Synagis (palivizumab)
Prophylaxis of respiratory syncytial virus (RSV) Indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients: with a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of respiratory syncytial virus (RSV) season; with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of respiratory syncytial virus (RSV) season; with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of respiratory syncytial virus (RSV) season. Limitations of use: The safety and efficacy of Synagis have not been established for treatment of RSV disease.

2 . Criteria

Product Name:Synagis	
Diagnosis	Premature Infants (without other indications)
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - Born prematurely at or before 29 weeks, 0 days gestation [2, B]

AND

2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season [A].

AND

3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region.

AND

4 - Patient has not received Beyfortus (nirsevimab) for the current RSV season [4]

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

Product Name:Synagis	
Diagnosis	Chronic Lung Disease of Prematurity
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - Chronic lung disease (CLD) of prematurity [2]

AND

2 - Born before 32 weeks, 0 days gestation [2]

AND

3 - Received greater than 21% oxygen supplementation for at least the first 28 days after birth

AND

4 - One of the following:

4.1 Age < 12 months at the start of the respiratory syncytial virus (RSV) season.

OR

4.2 Both of the following:

Age at least 12 to < 24 months at the start of the RSV season

Received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season

AND

5 - Prescribed by or in consultation with one of the following:

Pediatric pulmonologist

Neonatologist

Pediatric intensivist

Infectious disease specialist

AND

6 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region.

AND

7 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

Product Name:Synagis	
Diagnosis	Hemodynamically Significant Congenital Heart Disease
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - One of the following:

1.1 Age < 12 months at the start of the respiratory syncytial virus (RSV) season, with one of the following: [C] (persons of all ages).

1.1.1 All of the following:

Acyanotic heart failure

Receiving medication to control congestive heart failure

Patient will require a cardiac surgical procedure

OR

1.1.2 Moderate to severe pulmonary hypertension

OR

1.1.3 Cyanotic heart defect

OR

1.2 Both of the following*: [D]

Age < 24 months

Patient will or has undergone a cardiac transplantation during the respiratory syncytial virus (RSV)season

AND

2 - Prescribed by or in consultation with a pediatric cardiologist

AND

3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

AND

4 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. *ONE additional postoper ative dose allowed for patients undergoing cardiac transplantation, car diac bypass or extracorporeal membrane oxygenation. [A, D] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

Product Name:Synagis	
Diagnosis	Pulmonary Abnormality or Neuromuscular Disorder
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - Pulmonary abnormalities (e.g., pulmonary malformations, tracheoesophageal fistula, conditions requiring tracheostomy) or neuromuscular disease (e.g., cerebral palsy) [2]

AND

2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season.

AND

3 - Impaired ability to clear secretions from the upper airway due to an ineffective cough

AND

4 - Prescribed by or in consultation with one of the following:

Pediatric pulmonologist

Neurologist

AND

5 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

AND

6 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre

	vss/rsv/index.html) to confirm the start of RSV season based on regio n.

Product Name:Synagis	
Diagnosis	Immunocompromised Children
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - Prescriber attests that patient is immunocompromised

AND

2 - Age < 24 months

AND

3 - Prescribed by or in consultation with one of the following:

Pediatric pulmonologist

Infectious disease specialist

Pediatric intensivist

AND

4 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

AND

5 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

Product Name:Synagis	
Diagnosis	Children with Cystic Fibrosis
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis [2]

AND

2 - One of the following:

2.1 Both of the following:

Age < 12 months

Clinical evidence of chronic lung disease (CLD) and/or nutritional compromise (i.e., failure to thrive) **OR** **2.2** Both of the following: Age at least 12 to < 24 months Severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length < 10th percentile on pediatric growth chart [E] **AND** **3** - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region **AND** **4** - Patient has not received Beyfortus (nirsevimab) for the current RSV season	
Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

3 . Endnotes

Five monthly doses of palivizumab will provide more than 6 months of prophylactic serum palivizumab concentrations. Administration of more than five monthly doses is not recommended. If RSV season onset is in November, the first dose should be administered in November, and the fifth and final dose should be administered in March. If RSV season onset is in November and the first dose is given in January, the third and

final dose should be administered in March. In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV “season” in the state of Florida that could affect the timing of palivizumab administration. [2] For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report (MMWR), season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is at least 10% and RSV season offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is at least 10%. [3] NREVSS surveillance data can be viewed here (http://www.cdc.gov/surveillance/nrevss/rsv/)

Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days' gestation. [2]

The following conditions are NOT considered hemodynamically significant congenital heart disease: secundum atrial septal defect, small ventricular septal defect, pulmonary stenosis, uncomplicated aortic stenosis, mild coaractation of the aorta, and patent ductus arteriosus; lesions adequately corrected by surgery, unless continuing required medication for congestive heart failure; mild cardiomyopathy and not receiving medical therapy for the condition; children in the second year of life. [2]

Pediatric growth charts can be viewed here (http://www.cdc.gov/growthcharts/who_charts.htm)

Children undergoing these procedures should receive an additional dose of palivizumab as soon as possible after the procedure. Thereafter, doses should be administered monthly as scheduled. [2]

Monthly prophylaxis should be discontinued in any infant or child who experiences a breakthrough RSV hospitalization. [2]

Palivizumab prophylaxis is not recommended for prevention of health care-associated RSV disease. [2]

The burden of RSV disease and costs associated with transport from remote locations may result in a broader use of palivizumab for RSV prevention in Alaska Native populations and possibly in selected other American Indian populations. [2]

4 . References

Synagis Prescribing Information. Swedish Orphan Biovitrum AB (publ). Stockholm, Sweden September 2021.

Commitee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalizations for respiratory syncytial virus infection. Pediatrics. 2014 Aug;134(2):415-20. doi: 10.1542/peds.2014-1665.

Panozzo CA, Stockman LJ, et al. Use of respiratory syncytial virus surveillance data to optimize the timing of immunoprophylaxis. Pediatrics. 2010 Jul;126(1):e116-23.

Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices – United States, 2023. MMWR Morb Mortal Wkly Rep. 2023;72(34):920-925

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228995
Guideline Name	Tabrecta (capmatinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tabrecta (capmatinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

2 . Criteria

Product Name:Tabrecta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TABRECTA	CAPMATINIB HCL TAB 150 MG	21533716200320	Brand
TABRECTA	CAPMATINIB HCL TAB 200 MG	21533716200330	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Tabrecta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TABRECTA	CAPMATINIB HCL TAB 150 MG	21533716200320	Brand
TABRECTA	CAPMATINIB HCL TAB 200 MG	21533716200330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Tabrecta Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. March 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228994
Guideline Name	Tafinlar (dabrafenib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tafinlar (dabrafenib)
BRAF V600E mutation-positive unresectable or metastatic melanoma Indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma. **BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma** Indicated in combination with trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma. **BRAF V600E mutation-positive metastatic non-small cell lung cancer** Indicated in combination with trametinib for the treatment of patients with metastatic non-small cell lung

cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

BRAF V600E or V600K mutation-positive adjunctive treatment for melanoma Indicated for adjuvant treatment in combination with trametinib for patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

Anaplastic thyroid cancer (ATC) with BRAF V600E mutation Indicated in combination with trametinib for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

BRAF V600E mutation-positive unresectable or metastatic solid tumors Indicated, in combination with trametinib, for the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

BRAF V600E mutation-positive low-grade glioma Indicated, in combination with trametinib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

2 . Criteria

Product Name:Tafinlar	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - One of the following diagnoses: [2]

Unresectable melanoma

Metastatic melanoma

AND

2 - One of the following:

2.1 Cancer is BRAFV600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

OR

2.2 Both of the following:

2.2.1 Cancer is BRAFV600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

2.2.2 Medication is used in combination with Mekinist (trametinib)

Product Name:Tafinlar	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Tafinlar	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer

AND

2 - Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - Medication is used in combination with Mekinist (trametinib)

Product Name:Tafinlar	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Tafinlar	
Diagnosis	Adjunctive treatment for melanoma
Approval Length	12 Month [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Cancer is BRAF V600E mutation or V600K mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Involvement of lymph nodes following complete resection [2]

AND

4 - Used as adjunctive therapy

AND

5 - Medication is used in combination with Mekinist (trametinib)

Product Name:Tafinlar	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) [2]

AND

2 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Cancer may not be treated with standard locoregional treatment options

AND

4 - Medication is used in combination with Mekinist (trametinib)

Product Name:Tafinlar	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Tafinlar	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Patient is 1 year of age or older

AND

3 - Disease is one of the following:

unresectable

metastatic

AND

4 - Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options

AND

5 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Medication is used in combination with Mekinist (trametinib)

Product Name:Tafinlar	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand

TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Tafinlar	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Diagnosis of low-grade glioma

AND

2 - Patient is 1 year of age or older

AND

3 - Patient requires systemic therapy

AND

4 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Medication is used in combination with Mekinist (trametinib)

Product Name:Tafinlar	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

The recommended dosage of TAFINLAR is 150 mg orally taken twice daily in combination with trametinib until disease recurrence or unacceptable toxicity for up to 1 year for the adjuvant treatment of melanoma [1].

4 . References

Tafinlar Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2023.

National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 12, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233250
Guideline Name	Tagrisso (osimertinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	1/27/2016
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Tagrisso (osimertinib)
First-line Treatment of EGFR Mutation-Positive Metastatic Non-Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. **Previously Treated EGFR T790M Mutation-Positive Metastatic NSCLC** Indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy. **Adjuvant Treatment of EGFR Mutation-Positive Non-Small Cell Lung Cancer (NSCLC)** Indicated as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

First-line Treatment of EGFR Mutation-Positive Locally Advanced or Metastatic NSCLC Indicated in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 or exon 21 L858R mutations, as detected by an FDA-approved test.

Locally Advanced, Unresectable (Stage III) EGFR Mutation-Positive NSCLC Indicated for the treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

2 . Criteria

Product Name:Tagrisso	
Diagnosis	First-line Treatment of EGFR Mutation-Positive NSCLC
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAGRISSO	OSIMERTINIB MESYLATE TAB 40 MG (BASE EQUIVALENT)	21360068200320	Brand
TAGRISSO	OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT)	21360068200330	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

1.1.2 Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-

approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

1.2 All of the following:

1.2.1 Diagnosis of locally advanced NSCLC

AND

1.2.2 Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.2.3 Used in combination with both of the following:

Pemetrexed

Platinum-based chemotherapy (e.g., cisplatin, carboplatin)

Product Name:Tagrisso	
Diagnosis	Previously Treated EGFR T790M Mutation-Positive Metastatic NSCLC
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAGRISSO	OSIMERTINIB MESYLATE TAB 40 MG (BASE EQUIVALENT)	21360068200320	Brand
TAGRISSO	OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT)	21360068200330	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Patient has a known active epidermal growth factor receptor (EGFR) T790M mutation as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): [1-3]

Gilotrif (afatinib)*

Iressa (gefitinib)*

Tarceva (erlotinib)*

Vizimpro (dacomitinib)*

Product Name:Tagrisso	
Diagnosis	Adjuvant Treatment of EGFR Mutation-Positive Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAGRISSO	OSIMERTINIB MESYLATE TAB 40 MG (BASE EQUIVALENT)	21360068200320	Brand
TAGRISSO	OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT)	21360068200330	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Both of the following:

Patient is receiving as adjuvant therapy

Patient has had a complete surgical resection of the primary non-small cell lung cancer (NSCLC) tumor

Product Name:Tagrisso	
Diagnosis	Locally Advanced, Unresectable (Stage III) EGFR Mutation-Positive NSCLC
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAGRISSO	OSIMERTINIB MESYLATE TAB 40 MG (BASE EQUIVALENT)	21360068200320	Brand
TAGRISSO	OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT)	21360068200330	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

Locally advanced

Unresectable (Stage III)

AND

3 - Presence of known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy

Product Name:Tagrisso	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAGRISSO	OSIMERTINIB MESYLATE TAB 40 MG (BASE EQUIVALENT)	21360068200320	Brand
TAGRISSO	OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT)	21360068200330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Tagrisso prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. September 2024.

National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc.; 2014. Updated periodically. Available by subscription at: www.nccn.org. Accessed March 27, 2023.

National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Non-small cell lung cancer. v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 27, 2023.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-229073
Guideline Name	Taltz (ixekizumab) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Taltz	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand

TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 20 MG/0.25ML	9025055400E510	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 40 MG/0.5ML	9025055400E515	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

Greater than or equal to 3% body surface area involvement

Severe scalp psoriasis

Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

5 - Prescribed by or in consultation with a dermatologist

AND

6 - Both of the following:

6.1 One of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product*

One formulary ustekinumab product*

Skyrizi (risankizumab)

Tremfya (guselkumab)

Otezla (apremilast)

Sotyktu (deucravacitinib)

OR

6.1.2 Both of the following:

6.1.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

6.1.2.2 Documentation of positive clinical response to therapy as evidenced by ONE of the following [2]:

Reduction the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

Bimzelx (bimekizumab-bkzx)

Cosentyx (secukinumab)

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name:Taltz	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 20 MG/0.25ML	9025055400E510	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 40 MG/0.5ML	9025055400E515	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

Bimzelx (bimekizumab-bkzx)

Cosentyx (secukinumab)

Product Name:Taltz	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 20 MG/0.25ML	9025055400E510	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 40 MG/0.5ML	9025055400E515	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

Greater than or equal to 3% body surface area involvement

Severe scalp psoriasis

Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

5 - Prescribed by or in consultation with a dermatologist

AND

6 - Both of the following:

6.1 One of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product*

One formulary ustekinumab product*

Skyrizi (risankizumab)

Tremfya (guselkumab)

Otezla (apremilast)

Sotyktu (deucravacitinib)

OR

6.1.2 Both of the following:

6.1.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

6.1.2.2 Documentation of positive clinical response to therapy as evidenced by ONE of the following [2]:

Reduction the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

Bimzelx (bimekizumab-bkzx)

Cosentyx (secukinumab)

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name:Taltz	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

AND

4 - One of the following:

4.1 All of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product*

Simponi (golimumab)

One formulary ustekinumab product*

Skyrizi (risankizumab-rzaa)

Tremfya (guselkumab)

Rinvoq/LQ (upadacitinib)

Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Cosentyx (secukinumab)

AND

4.1.3 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE of the following:

Bimzelx (bimekizumab-bkzx)

Orencia (abatacept)

AND

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

Product Name:Taltz	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

Product Name:Taltz	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 20 MG/0.25ML	9025055400E510	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 40 MG/0.5ML	9025055400E515	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

AND

4 - One of the following:

4.1 All of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product*

Simponi (golimumab)

One formulary ustekinumab product*

Skyrizi (risankizumab-rzaa)

Tremfya (guselkumab)

Rinvoq/LQ (upadacitinib)

Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Cosentyx (secukinumab)

AND

4.1.3 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE of the following:

Bimzelx (bimekizumab-bkzx)

Orencia (abatacept)

AND

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

Product Name:Taltz	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product*

Simponi (golimumab)

Rinvoq (upadacitinib)

Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

Bimzelx (bimekizumab-bkzx)

Cosentyx (secukinumab)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

Notes	* Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. ** For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products

Product Name:Taltz	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

Product Name:Taltz	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 20 MG/0.25ML	9025055400E510	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 40 MG/0.5ML	9025055400E515	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product*

Simponi (golimumab)

Rinvoq (upadacitinib)

Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

Bimzelx (bimekizumab-bkzx)

Cosentyx (secukinumab)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

Notes	* Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. ** For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products

Product Name:Taltz	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ALL of the following:

Cimzia (certolizumab pegol)

Bimzelx (bimekizumab-bkzx)

Cosentyx (secukinumab)

Rinvoq (upadacitinib)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

Product Name:Taltz	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

Product Name:Taltz	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 80 MG/ML	9025055400D520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 80 MG/ML	9025055400E520	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 20 MG/0.25ML	9025055400E510	Brand
TALTZ	IXEKIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 40 MG/0.5ML	9025055400E515	Brand

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ALL of the following:

Cimzia (certolizumab pegol)

Bimzelx (bimekizumab-bkzx)

Cosentyx (secukinumab)

Rinvoq (upadacitinib)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

2 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products
Adalimumab-adaz
Hyrimoz
Hadlima
Adalimumab-fkjp
Formulary Ustekinumab Products
Stelara (ustekinumab)

3 . References

Taltz prescribing information. Eli Lilly and Company. Indianapolis, IN. August 2024.

Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

4 . Revision History

Date	Notes
12/20/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-233213
Guideline Name	Talvey (talquetamab-tgvs)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/18/2023
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Talvey (talquetamab-tgvs)
Multiple Myeloma Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name:Talvey

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALVEY	TALQUETAMAB-TGVS SUBCUTANEOUS SOLN 3 MG/1.5ML (2 MG/ML)	21352076802020	Brand
TALVEY	TALQUETAMAB-TGVS SUBCUTANEOUS SOLN 40 MG/ML	21352076802040	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Disease is one of the following:

Relapsed

Refractory

AND

3 - Patient has received at least four prior lines of therapy which include all of the following:

An immunomodulatory agent (e.g., lenalidomide, thalidomide)

A proteasome inhibitor (e.g., bortezomib, carfilzomib)

A CD38-directed monoclonal antibody (e.g., daratumumab)

Product Name:Talvey	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALVEY	TALQUETAMAB-TGVS SUBCUTANEOUS SOLN 3 MG/1.5ML (2 MG/ML)	21352076802020	Brand
TALVEY	TALQUETAMAB-TGVS SUBCUTANEOUS SOLN 40 MG/ML	21352076802040	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Talvey Prescribing Information. Janssen Biotech, Inc. Horsham, PA. August 2023.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-229163
Guideline Name	Talzenna (talazoparib) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	12/19/2018
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Talzenna (talazoparib)
Breast Cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for TALZENNA. **HRR Gene-mutated mCRPC** Indicated in combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

2 . Criteria

Product Name:Talzenna	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.25 MG (BASE EQUIVALENT)	21535580400110	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 1 MG (BASE EQUIVALENT)	21535580400120	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.5 MG (BASE EQUIVALENT)	21535580400114	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.75 MG (BASE EQUIVALENT)	21535580400118	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.1 MG (BASE EQUIVALENT)	21535580400105	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.35 MG (BASE EQUIVALENT)	21535580400112	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Lynparza

OR

2.2 For continuation of prior therapy

Product Name:Talzenna

Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.25 MG (BASE EQUIVALENT)	21535580400110	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 1 MG (BASE EQUIVALENT)	21535580400120	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.5 MG (BASE EQUIVALENT)	21535580400114	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.75 MG (BASE EQUIVALENT)	21535580400118	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.1 MG (BASE EQUIVALENT)	21535580400105	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.35 MG (BASE EQUIVALENT)	21535580400112	Brand

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)

AND

2 - Presence of homologous recombination repair (HRR) gene mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Taken in combination with Xtandi (enzalutamide)

Product Name:Talzenna	
Diagnosis	Breast Cancer, Prostate Cancer
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.25 MG (BASE EQUIVALENT)	21535580400110	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 1 MG (BASE EQUIVALENT)	21535580400120	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.5 MG (BASE EQUIVALENT)	21535580400114	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.75 MG (BASE EQUIVALENT)	21535580400118	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.1 MG (BASE EQUIVALENT)	21535580400105	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.35 MG (BASE EQUIVALENT)	21535580400112	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Talzenna	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.25 MG (BASE EQUIVALENT)	21535580400110	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 1 MG (BASE EQUIVALENT)	21535580400120	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.5 MG (BASE EQUIVALENT)	21535580400114	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.75 MG (BASE EQUIVALENT)	21535580400118	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.1 MG (BASE EQUIVALENT)	21535580400105	Brand
TALZENNA	TALAZOPARIB TOSYLATE CAP 0.35 MG (BASE EQUIVALENT)	21535580400112	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Lynparza

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

Talzenna Prescribing Information. Pfizer Labs. New York, NY. March 2024

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. v4.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 16, 2024.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228998
Guideline Name	Tarceva (erlotinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tarceva (erlotinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. Limitations of use: Safety and efficacy of Tarceva have not been established in patients with NSCLC whose tumors have other EGFR mutations. Tarceva is not recommended for use in combination with platinum-based chemotherapy. **Pancreatic Cancer** Indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer in combination with gemcitabine.

2 . Criteria

Product Name:Brand Tarceva, Generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARCEVA	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Generic
TARCEVA	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Generic
TARCEVA	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Generic

Approval Criteria

1 - Diagnosis of locally advanced or metastatic (stage III or IV) non-small cell lung cancer (NSCLC) [2]

AND

2 - Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions, exon 21 (L858R) substitution, exon 18 (G719X, G719) or exon 20 (S7681) mutation as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

Product Name:Brand Tarceva, Generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARCEVA	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Generic
TARCEVA	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Generic
TARCEVA	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Generic

Approval Criteria

1 - One of the following diagnoses:

Locally advanced pancreatic cancer

Unresectable pancreatic cancer

Metastatic pancreatic cancer

AND

2 - Used in combination with Gemzar (gemcitabine)

Product Name:Brand Tarceva, Generic erlotinib	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARCEVA	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Generic

TARCEVA	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Generic
TARCEVA	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Tarceva Prescribing Information. Genentech USA, Inc. South San Francisco, CA. October 2016.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-small cell lung cancer. v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 27, 2023.

Erlotinib Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. January 2019.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228999
Guideline Name	Targretin (bexarotene)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Targretin (bexarotene) capsules
Cutaneous T-Cell Lymphoma Indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.
Drug Name: Targretin (bexarotene) gel 1%
Cutaneous T-Cell Lymphoma Indicated for the topical treatment of cutaneous lesions in patients with cutaneous T-cell lymphoma (Stage 1A and 1B) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

2 . Criteria

Product Name:Brand Targretin capsules, Generic bexarotene capsules, Brand Targretin gel, Generic bexarotene Gel	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARGRETIN	BEXAROTENE CAP 75 MG	21708220000120	Brand
TARGRETIN	BEXAROTENE GEL 1%	90376220004020	Brand
BEXAROTENE	BEXAROTENE CAP 75 MG	21708220000120	Generic
BEXAROTENE	BEXAROTENE GEL 1%	90376220004020	Generic

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL) [A]

AND

2 - Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids {i.e., clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}, topical mechlorethamine, phototherapy] or systemic therapies [e.g., brentuximab vedotin, methotrexate])

AND

3 - Trial and failure, contraindication, or intolerance to generic Targretin (Applies to brand Targretin only)

Product Name:Brand Targretin capsules, Generic bexarotene capsules, Brand Targretin gel, Generic bexarotene Gel	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARGRETIN	BEXAROTENE CAP 75 MG	21708220000120	Brand
TARGRETIN	BEXAROTENE GEL 1%	90376220004020	Brand
BEXAROTENE	BEXAROTENE CAP 75 MG	21708220000120	Generic
BEXAROTENE	BEXAROTENE GEL 1%	90376220004020	Generic

Approval Criteria

1 - Patient does not show evidence of disease progression while on therapy

3 . Endnotes

Cutaneous T-cell lymphomas (CTCLs) are a group of non-Hodgkin's lymphomas (NHLs) primarily developing in the skin and at times progress to involve lymph nodes, blood, and visceral organs. Mycosis fungoides (MF) is the most common subtype and is usually associated with an indolent clinical course with intermittent, stable, or slow progression of the lesions. Extracutaneous involvement (lymph nodes, blood, or less commonly, other organs) or large cell transformation (LCT) may be seen in advanced-stage disease. Sezary Syndrome (SS) is a rare erythrodermic, leukemic variant of CTCL and is characterized by significant blood involvement, erythroderma, and often lymphadenopathy. Primary cutaneous CD30+ T cell lymphoproliferative disorders are also included as a subtype of CTCL. [3]

4 . References

Targretin prescribing information. Bausch Health US, LLC. Bridgewater, NJ. April 2020.

Targretin gel 1% prescribing information. Bausch Health US, LLC. Bridgewater, NJ. February 2020.

National Comprehensive Cancer Network (NCCN). Primary Cutaneous Lymphomas v.2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf Accessed on July 18, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228724
Guideline Name	Tarpeyo (budesonide) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tarpeyo (budesonide)
Primary Immunoglobulin A Nephropathy (IgAN) Indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

2 . Criteria

Product Name:Tarpeyo	
Approval Length	9 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARPEYO	BUDESONIDE DELAYED RELEASE CAP 4 MG	22100012006520	Brand

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy [A]

AND

2 - Patient is at risk for disease progression

AND

3 - Used to reduce the loss of kidney function

AND

4 - Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m2

AND

5 - ONE of the following:

5.1 Patient has been on a minimum 90-day trial of a maximally tolerated dose and will continue to receive therapy with one of the following: [2]

An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)

An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to both ACE inhibitors and ARBs

AND

6 - Trial and failure, contraindication, or intolerance to another glucocorticoid (e.g., methylprednisolone, prednisone)

AND

7 - Prescribed by or in consultation with a nephrologist

Product Name:Tarpeyo	
Approval Length	9 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TARPEYO	BUDESONIDE DELAYED RELEASE CAP 4 MG	22100012006520	Brand

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy [A]

AND

2 - Patient is at risk for disease progression

AND

3 - Used to reduce the loss of kidney function

AND

4 - Submission of medical records (e.g., chart notes) confirming estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m2

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

5.1 Patient has been on a minimum 90-day trial of a maximally tolerated dose and will continue to receive therapy with one of the following: [2]

An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)

An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to both ACE inhibitors and ARBs

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to another glucocorticoid (e.g., methylprednisolone, prednisone)

AND

7 - Prescribed by or in consultation with a nephrologist

3 . Endnotes

IgAN can only be diagnosed with a kidney biopsy. [2]

4 . References

Tarpeyo Prescribing Information. Calliditas Therapeutics AB. Stockholm, Sweden. December 2023.

Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021;100(4S):S1-S276.

Prior Authorization Guideline

Guideline ID	GL-229003
Guideline Name	Tasigna (nilotinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tasigna (nilotinib)
Newly diagnosed Ph+ Chronic Myeloid Leukemia Indicated for the treatment of adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. **Resistant or intolerant CML in chronic phase (CP) and accelerated phase (AP)** Indicated for the treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant to or intolerant to prior therapy that included imatinib. **Resistant or intolerant CML in chronic phase (CP) and accelerated phase (AP), Pediatric** Indicated for pediatric patients greater than or equal to 1 year of age with chronic phase and accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy.

2 . Criteria

Product Name:Tasigna	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TASIGNA	NILOTINIB HCL CAP 50 MG (BASE EQUIVALENT)	21531860200110	Brand
TASIGNA	NILOTINIB HCL CAP 150 MG (BASE EQUIVALENT)	21531860200115	Brand
TASIGNA	NILOTINIB HCL CAP 200 MG (BASE EQUIVALENT)	21531860200125	Brand

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive/BCR ABL positive (Ph+/BCR ABL) chronic myelogenous/myeloid leukemia (CML) (A)

AND

2 - Patient is 1 year of age or older

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to generic imatinib

OR

3.2 Continuation of prior therapy

Product Name:Tasigna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TASIGNA	NILOTINIB HCL CAP 50 MG (BASE EQUIVALENT)	21531860200110	Brand
TASIGNA	NILOTINIB HCL CAP 150 MG (BASE EQUIVALENT)	21531860200115	Brand
TASIGNA	NILOTINIB HCL CAP 200 MG (BASE EQUIVALENT)	21531860200125	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to generic imatinib

OR

2.2 Continuation of prior therapy

3 . Endnotes

BCR-ABL1 refers to a gene sequence found in an abnormal chromosome 22. The cause of chronic myelogenous leukemia (CML) can be traced to a single, specific genetic abnormality in one chromosome. The presence of the gene sequence known as BCR-ABL1 confirms the diagnosis of CML.

4 . References

Tasigna Prescribing Information. Novartis Pharmaceutical Corporation. East Hanover, NJ. February 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic Myelogenous Leukemia v.1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed March 27, 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228552
Guideline Name	Tavalisse (fostamatinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tavalisse (fostamatinib)
Chronic Immune Thrombocytopenia (ITP) Indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

2 . Criteria

Product Name:Tavalisse	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAVALISSE	FOSTAMATINIB DISODIUM TAB 100 MG (BASE EQUIVALENT)	85756040100310	Brand
TAVALISSE	FOSTAMATINIB DISODIUM TAB 150 MG (BASE EQUIVALENT)	85756040100320	Brand

Approval Criteria

1 - Diagnosis of one of the following:

Chronic immune thrombocytopenia (ITP) [A]

Relapsed/refractory ITP [3]

AND

2 - Baseline platelet count is less than 30,000/mcL [2-4]

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following: [1-4]

Corticosteroids (e.g., dexamethasone, prednisone)

Immune globulins (e.g., Gammaplex, Gammagard S/D)

Splenectomy

AND

4 - Patient’s degree of thrombocytopenia and clinical condition increase the risk of bleeding [3]

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Tavalisse	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAVALISSE	FOSTAMATINIB DISODIUM TAB 100 MG (BASE EQUIVALENT)	85756040100310	Brand
TAVALISSE	FOSTAMATINIB DISODIUM TAB 150 MG (BASE EQUIVALENT)	85756040100320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding

3 . References

Tavalisse Prescribing Information. Rigel Pharmaceuticals, Inc. South San Francisco, CA. November 2020.

Neunert C, Terrell D, Arnold D, et al. The American Society of Hematology 2019 Evidence-based practice guideline for immune thrombocytopenia. Available at: https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for. Accessed December 4, 2023.

Per clinical consult with hematologist/oncologist. June 20, 2018.

Bussel J, Arnold DM, Grossbard E, et al. Fostamatinib for the treatment of adult persistent and chronic immune thrombocytopenia: Results of two phase 3, randomized, placebo-controlled trials. Am J Hematol. 2018;93:921-30.

Immune thrombocytopenia (ITP) in adults: Clinical manifestations and diagnosis. UpToDate Website. Available at: www.uptodate.com. Accessed December 6, 2023.

Prior Authorization Guideline

Guideline ID	GL-229135
Guideline Name	Tavneos (avacopan) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	12/15/2021
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Tavneos (avacopan)
Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis Indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. Tavneos does not eliminate glucocorticoid use.

2 . Criteria

Product Name:Tavneos

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAVNEOS	AVACOPAN CAP 10 MG	85805510000120	Brand

Approval Criteria

1 - Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis:

Granulomatosis with polyangiitis (GPA)

Microscopic polyangiitis (MPA)

AND

2 - Diagnosis is confirmed by one of the following: [4]

ANCA test positive for proteinase 3 (PR3) antigen

ANCA test positive for myeloperoxidase (MPO) antigen

Tissue biopsy

AND

3 - Patient is receiving concurrent immunosuppressant therapy with one of the following: [1-3]

cyclophosphamide

rituximab

AND

4 - One of the following:

4.1 Patient is concurrently on glucocorticoids (e.g., prednisone)

OR

4.2 History of contraindication or intolerance to glucocorticoids (e.g., prednisone)

AND

5 - Prescribed by or in consultation with one of the following:

Nephrologist

Pulmonologist

Rheumatologist

Product Name:Tavneos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAVNEOS	AVACOPAN CAP 10 MG	85805510000120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab)

AND

3 - Prescribed by or in consultation with one of the following:

Nephrologist

Pulmonologist

Rheumatologist

Product Name:Tavneos	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TAVNEOS	AVACOPAN CAP 10 MG	85805510000120	Brand

Approval Criteria

1 - Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis:

Granulomatosis with polyangiitis (GPA)

Microscopic polyangiitis (MPA)

AND

2 - Diagnosis is confirmed by one of the following: [4]

ANCA test positive for proteinase 3 (PR3) antigen

ANCA test positive for myeloperoxidase (MPO) antigen

Tissue biopsy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming patient is receiving concurrent immunosuppressant therapy with one of the following: [1-3]

cyclophosphamide

rituximab

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming patient is concurrently on glucocorticoids (e.g., prednisone)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming contraindication or intolerance to glucocorticoids (e.g., prednisone)

AND

5 - Prescribed by or in consultation with one of the following:

Nephrologist

Pulmonologist

Rheumatologist

3 . References

Tavneos Prescribing Information. ChemoCentryx, Inc. San Carlos, CA. October 2021.

Jayne DRW, Merkel PA, Schall TJ, Bekker P; ADVOCATE Study Group. Avacopan for the Treatment of ANCA-Associated Vasculitis. N Engl J Med. 2021;384(7):599-609. doi:10.1056/NEJMoa2023386

Per clinical consult with rheumatologist November 17, 2021.

Falk RJ, Merkel PA, King TE. Granulomatosis with polyangiitis and microscopic polyangiitis: clinical manifestations and diagnosis. In: Post T, ed. UpToDate 2022. Accessed October 9, 2022.

Merkel PA, Kaplan AA. Granulomatosis with polyangiitis and microscopic polyangiitis: Induction and maintenance therapy. UpToDate 2022. Accessed October 9, 2022.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228553
Guideline Name	Tazverik (tazemetostat) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tazverik (tazemetostat)
Epithelioid Sarcoma Indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). **Follicular Lymphoma** Indicated for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies. Also indicated for the treatment of adult patients with R/R FL who have no satisfactory alternative treatment options. These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name:Tazverik	
Diagnosis	Epithelioid Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZVERIK	TAZEMETOSTAT HBR TAB 200 MG	21533675200320	Brand

Approval Criteria

1 - Diagnosis of epithelioid sarcoma

AND

2 - Disease is one of the following:

Metastatic

Locally advanced

AND

3 - Patient is not eligible for complete resection

AND

4 - Patient is 16 years of age or older

Product Name:Tazverik	
Diagnosis	Follicular Lymphoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZVERIK	TAZEMETOSTAT HBR TAB 200 MG	21533675200320	Brand

Approval Criteria

1 - Diagnosis of follicular lymphoma

AND

2 - Disease is one of the following:

Relapsed

Refractory

Product Name:Tazverik	
Diagnosis	Epithelioid Sarcoma, Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZVERIK	TAZEMETOSTAT HBR TAB 200 MG	21533675200320	Brand

Approval Criteria

1 - Patient does not show evidence of disease progression while on therapy

Product Name:Tazverik	
Diagnosis	Epithelioid Sarcoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TAZVERIK	TAZEMETOSTAT HBR TAB 200 MG	21533675200320	Brand

Approval Criteria

1 - Diagnosis of epithelioid sarcoma

AND

2 - Disease is one of the following:

Metastatic

Locally advanced

AND

3 - Patient is not eligible for complete resection

AND

4 - Patient is 16 years of age or older

Product Name:Tazverik	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TAZVERIK	TAZEMETOSTAT HBR TAB 200 MG	21533675200320	Brand

Approval Criteria

1 - Diagnosis of follicular lymphoma

AND

2 - Disease is one of the following:

Relapsed

Refractory

3 . References

Tazverik prescribing information. Epizyme, Inc. Cambridge, MA. December 2023.

Prior Authorization Guideline

Guideline ID	GL-233304
Guideline Name	Tecelra (afamitresgene autoleucel) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/16/2024
P&T Revision Date:	

1 . Indications

Drug Name: Tecelra (afamitresgene autoleucel)
Synovial sarcoma Indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 . Criteria

Product Name:Tecelra	
Diagnosis	Synovial Sarcoma
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TECELRA	AFAMITRESGENE AUTOLEUCEL IV SUSP 10,000,000,000 CELLS	21651006101820	Brand

Approval Criteria

1 - Diagnosis of synovial sarcoma

AND

2 - Disease is one of the following:

Unresectable

Metastatic

AND

3 - Both of the following:

3.1 Patient is HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P positive

AND

3.2 Patient does not have HLA-A*02:05P in either allele

AND

4 - Presence of MAGE-A4 antigen as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Patient has received prior therapy with one of the following:

An anthracycline (e.g. doxorubicin)

Ifosfamide

AND

6 - Patient is 16 years of age or older

AND

7 - Patient has never received Tecelra treatment in their lifetime

Product Name:Tecelra	
Diagnosis	Synovial Sarcoma
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TECELRA	AFAMITRESGENE AUTOLEUCEL IV SUSP 10,000,000,000 CELLS	21651006101820	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of synovial sarcoma

AND

2 - Disease is one of the following:

Unresectable

Metastatic

AND

3 - Submission of medical records (e.g., chart notes) confirming both of the following:

3.1 Patient is HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P positive

AND

3.2 Patient does not have HLA-A*02:05P in either allele

AND

4 - Submission of medical records (e.g., chart notes) confirming presence of MAGE-A4 antigen as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Submission of medical records (e.g., chart notes) or paid claims confirming patient has received prior therapy with one of the following:

An anthracycline (e.g. doxorubicin)

Ifosfamide

AND

6 - Patient is 16 years of age or older

AND

7 - Patient has never received Tecelra treatment in their lifetime

3 . References

Tecelra Prescribing Information. Adaptimmune LLC, Philadelphia, PA 19112. August 2024

Afamitresgene autoleucel for advanced synovial sarcoma and myxoid round cell liposarcoma (SPEARHEAD-1): an international, open-label, phase 2 trial D'Angelo, Sandra P et al. The Lancet, Volume 403, Issue 10435, 1460 - 1471

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-233279
Guideline Name	Tecfidera (dimethyl fumarate) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	5/20/2021
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Tecfidera (dimethyl fumarate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

2 . Criteria

Product Name:Generic dimethyl fumarate	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIMETHYL FUMARATE	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 120 MG	62405525006520	Generic
DIMETHYL FUMARATE	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 240 MG	62405525006540	Generic
DIMETHYL FUMARATE STARTERPACK	DIMETHYL FUMARATE CAPSULE DR STARTER PACK 120 MG & 240 MG	6240552500B320	Generic

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [4]

AND

2 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Brand Tecfidera	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 120 MG	62405525006520	Brand
TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 240 MG	62405525006540	Brand

TECFIDERA STARTER PACK	DIMETHYL FUMARATE CAPSULE DR STARTER PACK 120 MG & 240 MG	6240552500B320	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [3]

AND

2 - All of the following:

2.1 Trial and failure of at least 4 weeks, or intolerance to generic dimethyl fumarate

AND

2.2 Trial and failure of at least 4 weeks, or intolerance to at least one of the following disease-modifying therapies for MS: [A, 5]

Bafiertam (monomethyl fumarate)

Vumerity (diroximel fumarate)

AND

2.3 One of the following:

2.3.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to generic fingolimod

OR

2.3.2 For continuation of therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Brand Tecfidera, generic dimethyl fumarate	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 120 MG	62405525006520	Brand
DIMETHYL FUMARATE	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 120 MG	62405525006520	Generic
TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 240 MG	62405525006540	Brand
DIMETHYL FUMARATE	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 240 MG	62405525006540	Generic
DIMETHYL FUMARATE STARTERPACK	DIMETHYL FUMARATE CAPSULE DR STARTER PACK 120 MG & 240 MG	6240552500B320	Generic
TECFIDERA STARTER PACK	DIMETHYL FUMARATE CAPSULE DR STARTER PACK 120 MG & 240 MG	6240552500B320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - All of the following: (applies to Brand Tecfidera only)

2.1 Trial and failure of at least 4 weeks, or intolerance to generic dimethyl fumarate

AND

2.2 Trial and failure of at least 4 weeks, or intolerance to at least one of the following disease-modifying therapies for MS: [A, 5]

Bafiertam (monomethyl fumarate)

Vumerity (diroximel fumarate)

AND

2.3 One of the following:

2.3.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to generic fingolimod

OR

2.3.2 For continuation of therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Brand Tecfidera	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 120 MG	62405525006520	Brand
TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 240 MG	62405525006540	Brand
TECFIDERA STARTER PACK	DIMETHYL FUMARATE CAPSULE DR STARTER PACK 120 MG & 240 MG	6240552500B320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [3]

AND

2 - Both of the following:

2.1 Submission of medical records (e.g., chart notes) confirming objective information indicating a lack of adequate clinical response after at least a 4-week trial with generic dimethyl fumarate

AND

2.2 Valid clinical justification provided explaining how Brand Tecfidera is expected to provide benefit when generic dimethyl fumarate has not been shown to be effective despite having the same active ingredient

AND

3 - Submission of medical records (e.g., chart notes) or paid claims confirming failure after a trial of at least 4 weeks or intolerance to both of the following:

Bafiertam

Vumerity

AND

4 - One of the following:

4.1 Submission of medical records (e.g., chart notes) or paid claims confirming failure after a trial of at least 4 weeks, contraindication or intolerance to one formulary alternatives from the following:

Avonex (interferon beta-1a)

Betaseron (interferon beta-1b)

Copaxone/Glatopa (glatiramer acetate)

Fingolimod

Kesimpta (ofatumumab)

Mayzent (siponimod)

Zeposia (ozanimod)

OR

4.2 Both of the following:

4.2.1 Submission of medical records (e.g., chart notes) or paid claims confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

4.2.2 Patient demonstrates positive clinical response to therapy

AND

5 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

6 - Prescribed by or in consultation with a neurologist

3 . Endnotes

Although the trial results of Bafiertam and Vumerity were based off of Tecfidera, the consultant thinks that the two drugs should have the same efficacy and safety profile as Tecfidera since they were approved via the FDA 505(b)(2) pathway. [5]

The advantage of using combination disease-modifying therapy (DMT) compared to monotherapy DMT use has not been demonstrated, but there are safety concerns, such as reduced efficacy or disease aggravation, with combination use. [6, 7]

4 . References

Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.

National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed March 29, 2019.

Tecfidera Prescribing Information. Biogen Idec Inc. Cambridge, MA. March 2024.

Dimethyl Fumarate Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. February 2022.

Per clinical consultation with MS specialist, July 22, 2020.

Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. Mayo Clinic Proceedings, 89(2), 225-240.

Sorensen, P., Lycke, J., Erälinna, J., Edland, A., Wu, X., & Frederiksen, J. et al. (2011). Simvastatin as add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (SIMCOMBIN study): a placebo-controlled randomised phase 4 trial. The Lancet Neurology, 10(8), 691-701.

5 . Revision History

Date	Notes

1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228782
Guideline Name	Tepezza (teprotumumab-trbw)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tepezza (teprotumumab-trbw)
Thyroid Eye Disease (TED) Indicated for the treatment of thyroid eye disease regardless of Thyroid Eye Disease (TED) activity or duration.

2 . Criteria

Product Name:Tepezza	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

TEPEZZA	TEPROTUMUMAB-TRBW FOR IV SOLN 500 MG	30192070402120	Brand

Approval Criteria

1 - Diagnosis of thyroid eye disease (TED)

AND

2 - Trial and failure (minimum 4 weeks), contraindication or intolerance to at least one oral or IV glucocorticosteroid (e.g., prednisone, methylprednisolone)

AND

3 - Prescribed by or in consultation with one of the following: [3]

Endocrinologist

Ophthalmologist

AND

4 - Treatment with Tepezza has not exceeded a total of 8 infusions [A, 1]

3 . Endnotes

In the pivotal trials, patients were given intravenous infusions (10 mg/kg for first infusion and 20 mg/kg for the remaining 7 infusions) every 3 weeks for a total of 8 infusions. [1]

4 . References

Tepezza prescribing information. Horizon Therapeutics USA, Inc. Deerfield, IL. April 2023.

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Prior Authorization Guideline

Guideline ID	GL-229005
Guideline Name	Tepmetko (tepotinib) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tepmetko (tepotinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

2 . Criteria

Product Name:Tepmetko	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TEPMETKO	TEPOTINIB HCL TAB 225 MG	21533773100320	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations [A]

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to Tabrecta

OR

4.2 For continuation of prior therapy

Product Name:Tepmetko	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TEPMETKO	TEPOTINIB HCL TAB 225 MG	21533773100320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Tabrecta

OR

2.2 For continuation of prior therapy

Product Name:Tepmetko	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TEPMETKO	TEPOTINIB HCL TAB 225 MG	21533773100320	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations [A]

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Tabrecta

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . Endnotes

An FDA-approved test for detection of MET exon 14 skipping alterations in NSCLC for selecting patients for treatment with Tepmetko is not available. Testing for the presence of MET exon 14 skipping alterations in plasma specimens is recommended only in patients for whom a tumor biopsy cannot be obtained. [1]

4 . References

Tepmetko Prescribing Information. EMD Serono, Inc. Rockland, MA. February 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233451
Guideline Name	Teriparatide Products - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Forteo (teriparatide injection), Teriparatide (teriparatide injection)
Postmenopausal women with osteoporosis at high risk of fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, teriparatide reduces the risk of vertebral and nonvertebral fractures. **Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture** Indicated to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. **Men and women with glucocorticoid-induced osteoporosis at high risk for fracture** Indicated for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name:Brand Forteo, Brand Teriparatide, generic teriparatide	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture, Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TERIPARATIDE	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 620 MCG/2.48ML	3004407000D221	Brand
FORTEO	TERIPARATIDE SOLN PEN-INJ 560 MCG/2.24ML	3004407000D216	Brand
TERIPARATIDE	TERIPARATIDE SOLN PEN-INJ 560 MCG/2.24ML	3004407000D216	Generic

Approval Criteria

1 - Diagnosis of one of the following:

Postmenopausal osteoporosis or osteopenia

Primary or hypogonadal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions

Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - For Brand Forteo, trial and failure or intolerance to all of the following:

Brand Teriparatide

Generic teriparatide

Tymlos (abaloparatide)

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

4.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name:Brand Forteo, Brand Teriparatide, generic teriparatide	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture, Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

TERIPARATIDE	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 620 MCG/2.48ML	3004407000D221	Brand
FORTEO	TERIPARATIDE SOLN PEN-INJ 560 MCG/2.24ML	3004407000D216	Brand
TERIPARATIDE	TERIPARATIDE SOLN PEN-INJ 560 MCG/2.24ML	3004407000D216	Generic

Approval Criteria

1 - One of the following: [7,B]

1.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

1.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

AND

2 - For Brand Forteo, trial and failure or intolerance to all of the following:

Brand Teriparatide

Generic teriparatide

Tymlos (abaloparatide)

Product Name:Brand Forteo	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture, Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
FORTEO	TERIPARATIDE SOLN PEN-INJ 560 MCG/2.24ML	3004407000D216	Brand

Approval Criteria

1 - Diagnosis of one of the following:

Postmenopausal osteoporosis or osteopenia

Primary or hypogonadal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions

Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to all of the following:

Brand Teriparatide

Generic teriparatide

Tymlos (abaloparatide)

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

4.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name:Brand Forteo, Brand Teriparatide, generic teriparatide	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TERIPARATIDE	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 620 MCG/2.48ML	3004407000D221	Brand
FORTEO	TERIPARATIDE SOLN PEN-INJ 560 MCG/2.24ML	3004407000D216	Brand
TERIPARATIDE	TERIPARATIDE SOLN PEN-INJ 560 MCG/2.24ML	3004407000D216	Generic

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - History of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months [C]

AND

3 - One of the following: [8,A]

3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions

Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

Vertebral compression fracture

Fracture of the hip

Fracture of the distal radius

Fracture of the pelvis

Fracture of the proximal humerus

OR

3.4 One of the following:

Glucocorticoid dosing of at least 30 mg per day

Cumulative glucocorticoid dosing of at least 5 grams per year

AND

4 - Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [E]

AND

5 - For Brand Forteo, trial and failure or intolerance to both of the following:

Brand Teriparatide

Generic teriparatide

AND

6 - One of the following: [7,B]

6.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

6.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name:Brand Forteo, Brand Teriparatide, generic teriparatide	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TERIPARATIDE	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 620 MCG/2.48ML	3004407000D221	Brand
FORTEO	TERIPARATIDE SOLN PEN-INJ 560 MCG/2.24ML	3004407000D216	Brand

TERIPARATIDE	TERIPARATIDE SOLN PEN-INJ 560 MCG/2.24ML	3004407000D216	Generic

Approval Criteria

1 - One of the following: [7,B]

1.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

1.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

AND

2 - For Brand Forteo, trial and failure or intolerance to both of the following:

Brand Teriparatide

Generic teriparatide

Product Name:Brand Forteo	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
FORTEO	TERIPARATIDE SOLN PEN-INJ 560 MCG/2.24ML	3004407000D216	Brand

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - History of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months [C]

AND

3 - One of the following: [8,A]

3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions

Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

Vertebral compression fracture

Fracture of the hip

Fracture of the distal radius

Fracture of the pelvis

Fracture of the proximal humerus

OR

3.4 One of the following:

Glucocorticoid dosing of at least 30 mg per day

Cumulative glucocorticoid dosing of at least 5 grams per year

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [E]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

Brand Teriparatide

Generic teriparatide

AND

6 - One of the following: [7,B]

6.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

6.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

3 . Definitions

Definition	Description

Dual x-ray absorptiometry (DXA) [3]	A diagnostic test used to assess bone density at various skeletal sites using radiation exposure about one-tenth that of a standard chest X-ray. Central DXA (lumbar spine, hip) is the preferred measurement for definitive diagnosis of osteoporosis and for monitoring the effects of therapy.
Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean BMD of a young adult reference population (T-score between − 1.0 and − 2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration of bone tissue, decreased bone strength, bone fragility, and a consequent increase in fracture risk; BMD 2.5 or more standard deviations below the mean BMD of a young adult reference population (T-score at or below − 2.5).
Quantitative computed tomography (QCT) [3]	A diagnostic test used to assess volumetric bone density; reflects three-dimensional BMD. Usually used to assess the lumbar spine but has been adapted for other skeletal sites (e.g., hip). It is also possible to measure trabecular and cortical bone density in the periphery by peripheral QCT (pQCT) or high-resolution pQCT (HRpQCT).
T-score [3]	In describing BMD, the number of standard deviations above or below the mean BMD of a young adult reference population.
Z-score [3]	In describing BMD, the number of standard deviations above or below the mean BMD for persons of the same age, sex, and ethnicity.

4 . Endnotes

According to the American College of Rheumatology (ACR) guidelines for the prevention and treatment of glucocorticoid-induced osteoperosis, patients considered at high risk of fractures are as follows: (a) prior osteoporotic fracture, (b) a hip or spine BMD T-score less than or equal to -2.5,(c) FRAX 10-year risk of hip or major osteoporotic fracture at 3 percent or more and 20 percent or more, respectively, or (d) glucocorticoid use of at least 30mg per day or cumulative glucocorticoid doses of at least 5 grams per year. [9]

Use for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture. [1]

Most of the evidence supporting the efficacy of Forteo is based on studies evaluating its use in the treatment of glucocorticoid-induced osteoporosis (GIOP). To identify high risk patients, the GIOP studies (Saag et al, 2009) included patients with a history of

prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months. [5, 6]

According to AACE, alendronate, risedronate, zoledronic acid, or denosumab have evidence for broad spectrum anti-fracture efficacy (spine, hip, nonvertebral fracture risk reduction) and are appropriate as initial therapy for most patients at high risk of fracture. Raloxifene or ibandronate may be appropriate initial therapy in some cases where patients requiring drugs with spine-specific efficacy. Teriparatide has been shown to reduce the risk of vertebral and nonvertebral fractures. It is recommended for patients with very high fracture risk or those in whom bisphosphonate therapy has been ineffective. [2]

According to ACR, oral bisphosphonates are considered first-line for patients with glucocorticoid-induced osteoporosis at high risk for fractures. For patients in whom oral bisphosphonates are not appropriate, IV bisphosphonates should be considered. If bisphosphonate therapy is not appropriate, teriparatide should be considered. [9]

The WHO FRAX tool is available at www.shef.ac.uk/FRAX and incorporates multiple clinical factors that predict fracture risk, largely independent of BMD. [2]

5 . References

Forteo prescribing information. Eli Lilly and Company. Indianapolis, IN. April 2021.

American Association of Clinical Endocrinologists medical guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis: 2020 update. Available at: https://pro.aace.com/disease-state-resources/bone-and-parathyroid/clinical-practice-guidelines/clinical-practice. Accessed May 6, 2021.

The Bone Health and Osteoporosis Foundation (BHOF). Clinician's guide to prevention and treatment of osteoporosis. Washington (DC): The Bone Health and Osteoporosis Foundation (BHOF); 2022

North American Menopause Society. Management of postmenopausal osteoporosis in postmenopausal women: 2010 position statement of the North American Menopause Society. Menopause 2010;17(1):25-54.

Per clinical consult with bone disease specialist, September 26, 2011.

Saag KG, Zanchetta JR, Devogelaer JP, et al. Effects of teriparatide versus alendronate for treating glucocorticoid-induced osteoporosis: thirty-six-month results of a randomized, double-blind, controlled trial. Arthritis Rheum. 2009;60(11):3346-55.

Tymlos prescribing information. Radius Health, Inc. Waltham, MA. April 2021.

Per clinical consultation with endocrinologists. January 23 & 30, 2018.

American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis: 2022 edition. Available at: https://rheumatology.org/glucocorticoid-induced-osteoporosis-guideline. Accessed May 2023.

Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An endocrine society clinical practice guideline. J Clin Endocrin Metab. 2019; 104(5):1595-1622.

Teriparatide prescribing information. Alvogen, Inc. Morristown, NJ. November 2019.

6 . Revision History

Date	Notes
3/31/2025	GPI change

Prior Authorization Guideline

Guideline ID	GL-233343
Guideline Name	Testosterone
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	3/1/2025
P&T Approval Date:	5/17/2005
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Androderm (testosterone [T] patch), Androgel (T gel and pump), Fortesta (T gel), Natesto (T nasal gel), Testim (T gel), and Vogelxo (T gel and pump)
Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy or toxic damage from alcohol or heavy metals. These men usually have low testosterone serum levels and gonadotropins (FSH, LH) above the normal range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males less than 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure. **Hypogonadotropic hypogonadism (congenital or acquired)** Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous

testosterone. Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males less than 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Drug Name: Methitest (methyltestosterone) tablet

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Metastatic mammary cancer in females Indicated for secondary use in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchidectomy.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) is idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Drug Name: Depo-Testosterone (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related

hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Drug Name: Testopel (testosterone) pellet

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism" have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired)- idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism" have not been established.

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Drug Name: Aveed (testosterone undecanoate) injection

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous

testosterone. Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Drug Name: Testone CIK (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy. Limitations of Use: Safety and efficacy of testosterone cypionate in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of Use: Safety and efficacy of testosterone cypionate in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Drug Name: Xyosted (testosterone enanthate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter’s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Drug Name: Jatenzo (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established.

Drug Name: Tlando (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Drug Name: Kyzatrex (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous

testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Drug Name: Androderm, Androgel, Aveed, Azmiro, Depo-Testosterone, Fortesta, Methitest, Natesto, Testone CIK, Testim, Testopel, Vogelxo, Xyosted

Off Label Uses: Transgender male (female-to-male) - Gender Dysphoria/Gender Incongruence [11-12, 17, 28-29] Testosterone in 3 different formulations, including transdermal gel, significantly increased testosterone levels from the physiological range for women to the normal male range by week 30 of treatment in an observational study in transgender male (female-to-male) individuals. Hormonal sex reassignment therapy was associated with significantly fewer symptoms related to social distress, anxiety, and depression compared with those not receiving hormonal therapy in 1 cross-sectional study. Gender transition treatment can be initiated in adults and adolescents with confirmed persistent gender dysphoria/gender incongruence who have the capacity to make fully informed decisions and consent, usually by age 16 years, and have well-controlled, if any, mental health concerns. The goals of therapy are to suppress endogenous sex hormones of the designated gender and to replace these with endogenous sex hormones of the affirmed gender. Either parenteral or transdermal testosterone may be used to achieve and maintain testosterone levels in the normal male range. Avoid sustained supraphysiologic levels to reduce risk of adverse reactions. Compelling reasons may exist to initiate therapy at younger than 16 years; although, studies in this population are minimal. Initial therapy to undergo suppression of pubertal development at Tanner stages G2/B2 is suggested. Neither puberty suppression nor gender-affirming hormone therapies are recommended in pre-pubertal children.

Drug Name: Azmiro (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Azmiro in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Additionally, safety and efficacy of Azmiro in pediatric patients below the age of 12 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Azmiro in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Additionally, safety and efficacy of Azmiro in pediatric patients below the age of 12 years old have not been established.

2 . Criteria

Product Name:Androderm, Brand Androgel gel and pump (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Natesto, Generic testosterone gel 25 mg/2.5 g (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone gel pump (1%), Generic testosterone topical solution 30 mg/act, Generic testosterone gel 10 mg/act (2%), Aveed, Azmiro, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Fortesta, Brand Testim, Brand Testosterone Cypionate, Testone CIK, Testopel, Testosterone implant pellets, Xyosted, Brand Vogelxo

Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ANDRODERM	TESTOSTERONE TD PATCH 24HR 2 MG/24HR	23100030008503	Brand
ANDRODERM	TESTOSTERONE TD PATCH 24HR 4 MG/24HR	23100030008510	Brand
FORTESTA	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Brand
ANDROGEL	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
TESTIM	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
ANDROGEL	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 1.25 GM/ACT (1%)	23100030004040	Brand
ANDROGEL	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Brand

ANDROGEL	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Brand
VOGELXO	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
VOGELXO PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Generic
NATESTO	TESTOSTERONE NASAL GEL 5.5 MG/ACT	23100030004080	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Generic
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Brand
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Brand
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML	23100030202010	Generic
TESTOPEL	TESTOSTERONE IMPLANT PELLETS 75 MG	23100030008920	Brand
AVEED	TESTOSTERONE UNDECANOATE IM INJ IN OIL 750 MG/3ML (250MG/ML)	23100030802030	Brand
TESTONE CIK	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML KIT	23100030106415	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 50 MG/0.5ML	2310003020D520	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 75 MG/0.5ML	2310003020D530	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 100 MG/0.5ML	2310003020D540	Brand
TESTOSTERONE	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE TOPICAL SOLUTION	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 50 MG/ML	23100030102055	Brand

TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 100 MG/ML	23100030102060	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 150 MG/ML	23100030102065	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML	23100030102070	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 25 MG	23100030008910	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 50 MG	23100030008915	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 100 MG	23100030008930	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 200 MG	23100030008940	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 37.5 MG	23100030008912	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 87.5 MG	23100030008925	Brand
AZMIRO	TESTOSTERONE CYPIONATE IM SOLN PREF SYRINGE IN OIL 200 MG/ML	2310003010E530	Brand

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab** [7, 9]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

Bilateral orchiectomy

Panhypopituitarism

A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable

testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to both of the following (applies to Aveed, Azmiro, Testopel, Testosterone implant pellets, Testone CIK, Brand Depo-Testosterone, Brand Testosterone Cypionate only):

Generic testosterone cypionate

Generic testosterone enanthate

AND

6 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

Generic testosterone cypionate

Generic testosterone enanthate

AND

7 - Trial and failure or intolerance to generic testosterone gel (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, and Brand Natesto only)

Notes	**This may require treatment to be temporarily held.

Product Name:Generic testosterone cypionate	
Diagnosis	Male hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Generic

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab** [7, 8]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

Bilateral orchiectomy

Panhypopituitarism

A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

Notes	**This may require treatment to be temporarily held.

Product Name:Methitest, Generic methyltestosterone, Jatenzo, Kyzatrex, Tlando,Undecatrex	
Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	Brand
METHYLTESTOSTERONE	METHYLTESTOSTERONE CAP 10 MG	23100020000105	Generic
JATENZO	TESTOSTERONE UNDECANOATE CAP 158 MG	23100030800130	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 198 MG	23100030800135	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 237 MG	23100030800140	Brand
TLANDO	TESTOSTERONE UNDECANOATE CAP 112.5 MG	23100030800125	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 100 MG	23100030800124	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 150 MG	23100030800128	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Brand
UNDECATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Generic
KYZATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Generic

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab*** [7, 8]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab***

OR

4.3 Patient has a history of one of the following:

Bilateral orchiectomy

Panhypopituitarism

A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable

testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to both of the following:

Androderm (testosterone patch)

Generic testosterone gel

Notes	***This may require treatment to be temporarily held.

Product Name:Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Brand Fortesta, Generic testosterone gel 10 mg/act (2)%, Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Azmiro, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Testosterone Cypionate, Testone CIK, Testopel, Testosterone implant pellets, Tlando, Xyosted,Undecatrex

Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26 D]
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ANDRODERM	TESTOSTERONE TD PATCH 24HR 2 MG/24HR	23100030008503	Brand
ANDRODERM	TESTOSTERONE TD PATCH 24HR 4 MG/24HR	23100030008510	Brand

FORTESTA	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Brand
ANDROGEL	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
TESTIM	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	Brand
ANDROGEL	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 1.25 GM/ACT (1%)	23100030004040	Brand
ANDROGEL	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Brand
ANDROGEL	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Brand
VOGELXO	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
VOGELXO PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Generic
NATESTO	TESTOSTERONE NASAL GEL 5.5 MG/ACT	23100030004080	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Generic
METHYLTESTOSTERONE	METHYLTESTOSTERONE CAP 10 MG	23100020000105	Generic
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Brand
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Brand
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML	23100030202010	Generic
TESTOPEL	TESTOSTERONE IMPLANT PELLETS 75 MG	23100030008920	Brand
AVEED	TESTOSTERONE UNDECANOATE IM INJ IN OIL 750 MG/3ML (250MG/ML)	23100030802030	Brand
TESTONE CIK	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML KIT	23100030106415	Brand

TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 50 MG/0.5ML	2310003020D520	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 75 MG/0.5ML	2310003020D530	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 100 MG/0.5ML	2310003020D540	Brand
TESTOSTERONE	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE TOPICAL SOLUTION	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 50 MG/ML	23100030102055	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 100 MG/ML	23100030102060	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 150 MG/ML	23100030102065	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML	23100030102070	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 25 MG	23100030008910	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 50 MG	23100030008915	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 100 MG	23100030008930	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 200 MG	23100030008940	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 100 MG	23100030800124	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 150 MG	23100030800128	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 158 MG	23100030800130	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 198 MG	23100030800135	Brand

JATENZO	TESTOSTERONE UNDECANOATE CAP 237 MG	23100030800140	Brand
TLANDO	TESTOSTERONE UNDECANOATE CAP 112.5 MG	23100030800125	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 37.5 MG	23100030008912	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 87.5 MG	23100030008925	Brand
UNDECATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Generic
KYZATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Generic
AZMIRO	TESTOSTERONE CYPIONATE IM SOLN PREF SYRINGE IN OIL 200 MG/ML	2310003010E530	Brand

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

AND

3 - Trial and failure or intolerance to both of the following (applies to Aveed, Azmiro, Testopel, Testosterone implant pellets, Testone CIK, Brand Depo-Testosterone, Brand Testosterone Cypionate):

Generic testosterone cypionate

Generic testosterone enanthate

AND

4 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

Generic testosterone cypionate

Generic testosterone enanthate

AND

5 - Trial and failure or intolerance to generic testosterone (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, Brand Natesto only)

Product Name:Generic testosterone cypionate	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26 D]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Generic

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

Product Name:Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Brand Fortesta, Generic testosterone gel 10 mg/act (2)%, Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Azmiro, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Testosterone Cypionate, Generic testosterone cypionate, Testone CIK, Testopel, Testosterone implant pellets, Tlando, Xyosted,Undecatrex	
Diagnosis	Male hypogonadism, Gender dysphoria/Gender incongruence

Approval Length	12 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ANDRODERM	TESTOSTERONE TD PATCH 24HR 2 MG/24HR	23100030008503	Brand
ANDRODERM	TESTOSTERONE TD PATCH 24HR 4 MG/24HR	23100030008510	Brand
FORTESTA	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Brand
ANDROGEL	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
TESTIM	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	Brand
ANDROGEL	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 1.25 GM/ACT (1%)	23100030004040	Brand
ANDROGEL	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Brand
ANDROGEL	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Brand
VOGELXO	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
VOGELXO PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Generic
NATESTO	TESTOSTERONE NASAL GEL 5.5 MG/ACT	23100030004080	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Generic
METHYLTESTOSTERONE	METHYLTESTOSTERONE CAP 10 MG	23100020000105	Generic
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Brand

TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Generic
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Generic
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML	23100030202010	Generic
TESTOPEL	TESTOSTERONE IMPLANT PELLETS 75 MG	23100030008920	Brand
AVEED	TESTOSTERONE UNDECANOATE IM INJ IN OIL 750 MG/3ML (250MG/ML)	23100030802030	Brand
TESTONE CIK	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML KIT	23100030106415	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 50 MG/0.5ML	2310003020D520	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 75 MG/0.5ML	2310003020D530	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 100 MG/0.5ML	2310003020D540	Brand
TESTOSTERONE	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE TOPICAL SOLUTION	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 50 MG/ML	23100030102055	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 100 MG/ML	23100030102060	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 150 MG/ML	23100030102065	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML	23100030102070	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 25 MG	23100030008910	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 50 MG	23100030008915	Brand

TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 100 MG	23100030008930	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 200 MG	23100030008940	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 158 MG	23100030800130	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 198 MG	23100030800135	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 237 MG	23100030800140	Brand
TLANDO	TESTOSTERONE UNDECANOATE CAP 112.5 MG	23100030800125	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 100 MG	23100030800124	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 150 MG	23100030800128	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 37.5 MG	23100030008912	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 87.5 MG	23100030008925	Brand
UNDECATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Generic
KYZATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Generic
AZMIRO	TESTOSTERONE CYPIONATE IM SOLN PREF SYRINGE IN OIL 200 MG/ML	2310003010E530	Brand

Approval Criteria

1 - One of the following:

1.1 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.2 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

OR

1.3 Both of the following:

1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.3.2 One of the following:

1.3.2.1 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.3.2.2 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

2 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

Generic testosterone cypionate

Generic testosterone enanthate

Product Name:Methitest, Generic testosterone enanthate, Testopel, Testosterone implant pellets, Generic methyltestosterone, Brand Testosterone Cypionate [off-label]	
Diagnosis	Delayed puberty [E]
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	Brand
METHYLTESTOSTERONE	METHYLTESTOSTERONE CAP 10 MG	23100020000105	Generic
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML	23100030202010	Generic
TESTOPEL	TESTOSTERONE IMPLANT PELLETS 75 MG	23100030008920	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 50 MG/ML	23100030102055	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 100 MG/ML	23100030102060	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 150 MG/ML	23100030102065	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML	23100030102070	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 25 MG	23100030008910	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 50 MG	23100030008915	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 100 MG	23100030008930	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 200 MG	23100030008940	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 37.5 MG	23100030008912	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 87.5 MG	23100030008925	Brand

Approval Criteria

1 - Diagnosis of delayed puberty [A]

AND

2 - Male patient at birth [C]

AND

3 - Trial and failure or intolerance to both of the following (applies to Testopel and Testosterone implant pellets only):

Generic testosterone cypionate [F]

Generic testosterone enanthate

Product Name:Generic testosterone cypionate [off-label]	
Diagnosis	Delayed puberty [E]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Generic

Approval Criteria

1 - Diagnosis of delayed puberty [A]

AND

2 - Male patient at birth [C]

Product Name:Methitest, Generic methyltestosterone, Generic testosterone enanthate	
Diagnosis	Inoperable breast cancer in women
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	Brand
METHYLTESTOSTERONE	METHYLTESTOSTERONE CAP 10 MG	23100020000105	Generic

TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML	23100030202010	Generic

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Breast cancer is inoperable

AND

3 - Used for palliative treatment

AND

4 - Female patient at birth [C]

3 . Endnotes

Delayed puberty is defined as the lack of the initial signs of sexual maturation by an age that is more than 2-2.5 standard deviations above the mean for the population (traditionally, the age of 14 years in boys and 13 years in girls). In most cases, delayed puberty is not due to an underlying pathology, but instead represents an extreme end of the normal spectrum of pubertal timing, a developmental pattern referred to as constitutional delay of growth and puberty (CDGP). CDGP is the most common cause of delayed puberty in both sexes, but it can be diagnosed only after underlying conditions have been ruled out. Management of CDGP may involve expectant observation or therapy with low-dose sex steroids. [9]

Initial authorization of 6 months, and reauthorization of 12 months is based on the Endocrine Society's Clinical Practice Guideline's recommendation to monitor testosterone level 3 to 6 months after initiation of testosterone therapy, and then annually to assess whether symptoms have responded to treatment and whether the patient is suffering from any adverse effects. [8]

The gender criteria in place for male hypogonadism, delayed puberty, and inoperable breast cancer are to ensure safe and effective medication utilization due to FDA-approved labeling supporting the gender restriction [refer to individual Package Inserts]. Age and/or gender criteria will remain in the guideline, consistent with the following direction approved by OptumRx Legal & Regulatory: “Age and gender edits in place due to FDA safety guidance, labeling or supported by medical literature to satisfy medical necessity criteria would not be inconsistent with the [Section 1557 HCR non-discrimination] regulation."

According to DRUGDEX, for the treatment of transgender male (female-to-male) patients with gender dysphoria, various forms and dosages of testosterone have been used. [12] Clinical studies have also demonstrated the efficacy of several different androgen preparations to induce masculinization in female-to-male transgender persons. Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism. Either parenteral or transdermal preparations can be used to achieve testosterone values in the normal male range. [11]

An X-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal center [19-20].

Per consult with specialist, the pharmacokinetics of T. cypionate and T. enanthate are quite similar and physiologically produce similar results. The two agents are very close in efficacy and behavioral effects. Although T. cypionate isn't FDA-approved for delayed puberty, it is used in practice due to its similarity to T. enanthate. [25]

4 . References

Androderm Prescribing Information. Allergan Inc. Madison, NJ. May 2020.

Androgel Prescribing Information. Abbvie, Inc. North Chicago, IL. May 2019.

Androgel 1.62% Prescribing Information. AbbVie Inc. North Chicago, IL. February 2019.

Fortesta Prescribing Information. Endo Pharmaceuticals. Malvern, PA. June 2020.

Methitest Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. October 2018.

Testim Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. August 2021.

Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency: AUA guideline. J Urol 2018; S0022-5347(18)42817-0.

Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2018; 103(5):1715-1744.

Palmert MR, Dunkel L. Clinical practice. Delayed puberty. N Engl J Med. 2012; 2;366(5):443-53.

Vogelxo Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. April 2020.

Hembree, Wylie C, et al. "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline." J Clin Endocrinol Metab. November 2017, 102(11):3869-3903.

DRUGDEX ® [Internet database]. Greenwood Village, Colo: Thomson MICROMEDEX, updated periodically. Accessed February 7, 2022.

Natesto Prescribing Information. Trimel BioPharma SRL. Eaglewood, CO. September 2017.

Testosterone Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. July 2017.

Testosterone Pump Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. July 2017.

Methyltestosterone Prescribing Information. Impax Generics. Hayward, CA. January 2017.

Coleman E, Bockting W, Botzer M et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. International Journal of Transgenderism. 13:165-232, 2011.

Depo-Testosterone Prescribing information. Pfizer. New York, NY. November 2018.

Testosterone Enanthate Prescribing Information. Actavis Pharma, Inc. Corona, CA. December 2017.

Testopel Prescribing Information. Slate Pharma. Rye, NY. August 2018.

Aveed Prescribing Information. Endo Pharmaceuticals Solutions Inc. August 2021.

Testone CIK Prescribing Information. Asclemed USA, Inc. Torrance, CA. November 2018.

Xyosted Prescribing Information. Antares Pharma, Inc. Ewing, NJ. November 2019.

Jatenzo Prescribing Information. Clarus Therapeutics, Inc. Northbrook, IL. June 2019.

Per clinical consultation with endocrinology specialist, March 02, 2020.

World Health Organization. ICD-11: International classification of diseases (11th revision).

Tlando Prescribing Information. Antares Pharma, Inc. Ewing, NJ. March 2022.

Deutsch, MB, Amato P, Coureu M, et al. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People; 2nd edition. UCSF Gender Affirming Health Program, Department of Family and Community Medicine, University of California San Francisco. June 2016

Health Care for Transgender and Gender Diverse Individuals: ACOG Committee Opinion, Number 823. American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice.137(3):e75-e88, 2021

Kyzatrex Prescribing Information. Marius Pharmaceuticals. Raleigh, NC. July 2022.

Azmiro Prescribing Information. Azurity Pharmaceuticals, Inc. Woburn, MA. May 2024.

5 . Revision History

Date	Notes
2/26/2025	Quartz Comm and EHB copied to mirrow OptumRx and EHB

Tevimbra (tislelizumab)

Prior Authorization Guideline

Guideline ID	GL-233307
Guideline Name	Tevimbra (tislelizumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/16/2024
P&T Revision Date:	

1 . Indications

Drug Name: Tevimbra (tislelizumab)
Esophageal Squamous Cell Carcinoma Indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor

2 . Criteria

Product Name:Tevimbra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TEVIMBRA	TISLELIZUMAB-JSGR IV SOLN 100 MG/10ML	21357967002020	Brand

Approval Criteria

1 - Diagnosis of esophageal squamous cell carcinoma

AND

2 - Disease is one of the following:

Unresectable

Metastatic

AND

3 - Patient has received prior systemic chemotherapy

AND

4 - Patient has not previously been treated with a PD-(L)1 inhibitor (e.g., Keytruda, Opdivo)

Product Name:Tevimbra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TEVIMBRA	TISLELIZUMAB-JSGR IV SOLN 100 MG/10ML	21357967002020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Tevimbra Prescribing Information. BeiGene USA, Inc. San Mateo, CA. March 2024.

4 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228725
Guideline Name	Tezspire (tezepelumab-ekko) - PA
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tezspire (tezepelumab-ekko) injection, for subcutaneous use
Severe Asthma Indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. Limitations of Use: Tezspire is not indicated for the relief of acute bronchospasm or status asthmaticus.

2 . Criteria

Product Name:Tezspire	
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TEZSPIRE	TEZEPELUMAB-EKKO SUBCUTANEOUS SOLN PREF SYR 210 MG/1.91ML	4460807525E520	Brand
TEZSPIRE	TEZEPELUMAB-EKKO SUBCUTANEOUS SOLN AUTO-INJ 210 MG/1.91ML	4460807525D520	Brand

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - One of the following: [2,3]

2.1 Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months

OR

2.2 Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is 12 years of age or older

AND

3 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

3.1 Both of the following: [2,3]

High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day)

Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

3.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg]) [B]

AND

5 - Prescribed by or in consultation with one of the following:

Pulmonologist

Allergist/Immunologist

Product Name:Tezspire	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TEZSPIRE	TEZEPELUMAB-EKKO SUBCUTANEOUS SOLN PREF SYR 210 MG/1.91ML	4460807525E520	Brand
TEZSPIRE	TEZEPELUMAB-EKKO SUBCUTANEOUS SOLN AUTO-INJ 210 MG/1.91ML	4460807525D520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications [4]

AND

3 - Prescribed by or in consultation with one of the following:

Pulmonologist

Allergist/Immunologist

3 . Endnotes

The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, after initiation of treatment, patients should be re-evaluated in 3 to 6 months. [4]

The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention guideline recommend patients with severe asthma should be treated with maximal optimized high dose ICS-LABA therapy. [4]

4 . References

Tezspire (tezepelumab-ekko) Prescribing Information. Amgen Inc, Thousand Oaks, CA. May 2023

Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in Adults and Adolescents with Severe, Uncontrolled Asthma. N Engl J Med. 2021;384(19):1800-1809.

Corren J, Parnes JR, Wang L, et al. Tezepelumab in Adults with Uncontrolled Asthma. N Engl J Med. 2017;377(10):936-946.

Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2023 update). 2023 www.ginasthma.org. Accessed 13 February 2024.

Prior Authorization Guideline

Guideline ID	GL-229004
Guideline Name	Thalomid (thalidomide)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Thalomid (thalidomide)
Erythema Nodosum Leprosum (ENL) Indicated for the acute treatment of the cutaneous manifestations of moderate to severe ENL. Not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. Also indicated as a maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. **Newly Diagnosed Multiple Myeloma** Indicated in combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma.

2 . Criteria

Product Name:Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
THALOMID	THALIDOMIDE CAP 50 MG	99392070000120	Brand
THALOMID	THALIDOMIDE CAP 100 MG	99392070000130	Brand
THALOMID	THALIDOMIDE CAP 150 MG	99392070000135	Brand
THALOMID	THALIDOMIDE CAP 200 MG	99392070000140	Brand

Approval Criteria

1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL) with cutaneous manifestations

AND

2 - Thalomid is not used as monotherapy if moderate to severe neuritis is present

Product Name:Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
THALOMID	THALIDOMIDE CAP 50 MG	99392070000120	Brand
THALOMID	THALIDOMIDE CAP 100 MG	99392070000130	Brand
THALOMID	THALIDOMIDE CAP 150 MG	99392070000135	Brand
THALOMID	THALIDOMIDE CAP 200 MG	99392070000140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
THALOMID	THALIDOMIDE CAP 50 MG	99392070000120	Brand
THALOMID	THALIDOMIDE CAP 100 MG	99392070000130	Brand
THALOMID	THALIDOMIDE CAP 150 MG	99392070000135	Brand
THALOMID	THALIDOMIDE CAP 200 MG	99392070000140	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Used in combination with dexamethasone, unless the patient has an intolerance to steroids

Product Name:Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
THALOMID	THALIDOMIDE CAP 50 MG	99392070000120	Brand

THALOMID	THALIDOMIDE CAP 100 MG	99392070000130	Brand
THALOMID	THALIDOMIDE CAP 150 MG	99392070000135	Brand
THALOMID	THALIDOMIDE CAP 200 MG	99392070000140	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Thalomid Prescribing Information. Celgene Corporation. Summit, NJ. December 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228556
Guideline Name	Thyroid Agents
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Levothyroxine Sodium capsules
Hypothyroidism Indicated as replacement therapy in adults and pediatric patients 6 years and older with primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Limitations of Use: Not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis. **Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression** Indicated as an adjunct to surgery and radioiodine therapy in the management of adults and pediatric patients 6 years and older with thyrotropin-dependent well-differentiated thyroid cancer. Limitations of Use: Not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with may induce hyperthyroidism.
Drug Name: Thyquidity (levothyroxine sodium) oral solution
Hypothyroidism Indicated as a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Limitations of Use: Not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.

Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression Indicated as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer. Limitations of Use: Not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with Thyquidity may induce hyperthyroidism.

2 . Criteria

Product Name:Brand Levothyroxine capsules, Brand Thyquidity oral solution	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 13 MCG	28100010100105	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 25 MCG	28100010100110	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 50 MCG	28100010100115	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 75 MCG	28100010100120	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 88 MCG	28100010100125	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 100 MCG	28100010100130	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 112 MCG	28100010100135	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 125 MCG	28100010100140	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 137 MCG	28100010100145	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 150 MCG	28100010100150	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 175 MCG	28100010100155	Generic
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM CAP 200 MCG	28100010100160	Generic
THYQUIDITY	LEVOTHYROXINE SODIUM ORAL SOLUTION 100 MCG/5ML	28100010102023	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (minimum 30 days supply) or intolerance to generic levothyroxine tablets

3 . Endnotes

This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. [1]

4 . References

Levothyroxine Sodium capsule Prescribing Information. Lannett Company Inc. Philadelphia, PA. November 2021.

Thyquidity Prescribing Information. Vertice Specialty Group. Largo, FL. February 2021.

Tibsovo (ivosidenib)

Prior Authorization Guideline

Guideline ID	GL-228558
Guideline Name	Tibsovo (ivosidenib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tibsovo (ivosidenib)
Newly-Diagnosed Acute Myeloid Leukemia (AML) Indicated in combination with azacitidine or as monotherapy for the treatment of newly diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. **Relapsed or Refractory Acute Myeloid Leukemia (AML)** Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. **Locally Advanced or Metastatic Cholangiocarcinoma** Indicated for the treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. **Relapsed or Refractory Myelodysplastic Syndromes (MDS)** Indicated for the treatment of adult patients with relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

2 . Criteria

Product Name:Tibsovo	
Diagnosis	Newly-Diagnosed Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TIBSOVO	IVOSIDENIB TAB 250 MG	21534940000320	Brand

Approval Criteria

1 - Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

AND

2 - Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - One of the following:

3.1 Patient is greater than or equal to 75 years old

OR

3.2 Patient has comorbidities that preclude use of intensive induction chemotherapy [A]

Product Name:Tibsovo	
Diagnosis	Relapsed or Refractory Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TIBSOVO	IVOSIDENIB TAB 250 MG	21534940000320	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Disease is one of the following:

Relapsed

Refractory

AND

3 - Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

Product Name:Tibsovo	
Diagnosis	Locally Advanced or Metastatic Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

TIBSOVO	IVOSIDENIB TAB 250 MG	21534940000320	Brand

Approval Criteria

1 - Diagnosis of cholangiocarcinoma

AND

2 - Disease is one of the following:

Locally Advanced

Metastatic

AND

3 - Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

4 - Patient has been previously treated

Product Name:Tibsovo	
Diagnosis	Relapsed or Refractory Myelodysplastic Syndromes (MDS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TIBSOVO	IVOSIDENIB TAB 250 MG	21534940000320	Brand

Approval Criteria

1 - Diagnosis of Myelodysplastic Syndromes (MDS)

AND

2 - Disease is one of the following:

Relapsed

Refractory

AND

3 - Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

Product Name:Tibsovo	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TIBSOVO	IVOSIDENIB TAB 250 MG	21534940000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

Examples of comorbid conditions are severe cardiac or pulmonary disease, baseline ECOG performance status greater than or equal to 2, hepatic impairment with bilirubin greater than 1.5 times the upper limit of normal, or creatinine clearance less than 45 mL/min. [1]

4 . References

Tibsovo prescribing information. Servier Pharmaceuticals LLC, Boston, MA. October 2023.

U.S. Food and Drug Administration: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/ucm301431.htm. Accessed June 15, 2022.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. Version 2.2022. Accessed June 15, 2022.

Prior Authorization Guideline

Guideline ID	GL-229009
Guideline Name	Tobramycin Inhaled Products - ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Bethkis (tobramycin) Inhalation Solution
Cystic Fibrosis Indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of six years, patients with FEV 1 less than 40% or greater than 80% predicted, or patients colonized with Burkholderia cepacia.
Drug Name: Kitabis Pak (co-packaged tobramycin inhalation solution PARI LC PLUS reusable nebulizer)
Cystic fibrosis Indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with P. aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 less than 25% or greater than 75% predicted, or patients colonized with Burkholderia cepacia.
Drug Name: TOBI (tobramycin) Inhalation Solution
Cystic fibrosis Indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with Pseudomonas aeruginosa. Safety and efficacy have not been

demonstrated in patients under the age of 6 years, patients with forced expiratory volume in 1 second (FEV1) <25% or >75% predicted, or patients colonized with Burkholderia cepacia.

2 . Criteria

Product Name:Brand Bethkis Inhalation Solution, Kitabis Pak, Brand TOBI Inhalation Solution	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TOBI	TOBRAMYCIN NEBU SOLN 300 MG/5ML	07000070002520	Brand
KITABIS PAK	TOBRAMYCIN NEBU SOLN 300 MG/5ML	07000070002520	Brand
BETHKIS	TOBRAMYCIN NEBU SOLN 300 MG/4ML	07000070002530	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication.

AND

2 - Trial and failure of a minimum 30 day supply, or intolerance to both of the following:

generic tobramycin 300 mg/4 ml nebulized solution

generic tobramycin 300 mg/5 ml nebulized solution

Product Name:Brand Bethkis Inhalation Solution, Kitabis Pak, Brand TOBI Inhalation Solution	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TOBI	TOBRAMYCIN NEBU SOLN 300 MG/5ML	07000070002520	Brand
KITABIS PAK	TOBRAMYCIN NEBU SOLN 300 MG/5ML	07000070002520	Brand
BETHKIS	TOBRAMYCIN NEBU SOLN 300 MG/4ML	07000070002530	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication.

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure of a minimum 30 day supply, or intolerance to both of the following:

generic tobramycin 300 mg/4 ml nebulized solution

generic tobramycin 300 mg/5 ml nebulized solution

3 . References

Kitabis Pak Prescribing Information. Catalent Pharma Solutions, LLC. Woodstock, IL. April 2023.

TOBI Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. February 2023.

Bethkis Prescribing Information. Chiesi USA, Inc. Woodstock, IL. February 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228621
Guideline Name	Tocilizumab
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Actemra IV & SC (tocilizumab), Tofidence IV (tocilizumab-bavi), Tyenne IV & SC (tocilizumab-aazg)
Rheumatoid arthritis (RA) Indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. **Systemic Juvenile Idiopathic Arthritis (SJIA)** Indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older. **Giant Cell Arteritis (GCA) - Off Label for Tofidence** Indicated for the treatment of giant cell arteritis (GCA) in adult patients.
Drug Name: Actemra SC (tocilizumab)

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Indicated for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).
Drug Name: Tyenne SC (tocilizumab-aazg)
Off Label Uses: Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Tocilizumab SC has been used for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).
Drug Name: Actemra IV (tocilizumab)
Cytokine Release Syndrome Indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older. **Coronavirus Disease 2019 (COVID-19)** Indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
Drug Name: Tofidence IV (tocilizumab-bavi), Tyenne IV (tocilizumab-aazg)
Off Label Uses: Cytokine Release Syndrome Tocilizumab IV has been used for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older [1]. **Coronavirus Disease 2019 (COVID-19)** Tocilizumab IV has been used for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) [1].

2 . Criteria

Product Name:Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

methotrexate

leflunomide

sulfasalazine

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

Cimzia (certolizumab pegol)

Enbrel (etanercept)

One formulary adalimumab product

Rinvoq (upadacitinib)

Simponi (golimumab)

Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

5 - Both of the following: (Applies to Tofidence IV, Tyenne IV or SC only)

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

5.2 Submission of medical records documenting why the covered product has not been effective

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. ** For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products

Product Name:Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [5]:

leflunomide

methotrexate

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

Enbrel (etanercept)

One formulary adalimumab product

Rinvoq/LQ (upadacitinib)

Xeljanz (tofacitinib)

OR

4.2 For continuation of therapy, defined as no more than a 45-day gap in therapy

AND

5 - Both of the following: (Applies to Tofidence IV, Tyenne IV or SC only)

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

5.2 Submission of medical records documenting why the covered product has not been effective

Notes	* Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T

	NF inhibitor. ** For review process only: Refer to the table in the Background sectio n for carrier-specific formulary adalimumab products

Product Name:Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name:Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

Minimum duration of a 3-month trial and failure of methotrexate

Minimum duration of a 1-month trial of nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)

Minimum duration of a 2-week trial of systemic glucocorticoid (e.g., prednisone)

AND

4 - Both of the following: (Applies to Tofidence IV, Tyenne IV or SC only)

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

4.2 Submission of medical records documenting why the covered product has not been effective

Product Name:Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand

ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

Product Name:Actemra IV or SC, Tofidence IV [off-label], Tyenne IV or SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand

ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Diagnosis of giant cell arteritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to a glucocorticoid

AND

4 - Both of the following: (Applies to Tofidence IV, Tyenne IV or SC only)

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

4.2 Submission of medical records documenting why the covered product has not been effective

Product Name:Actemra IV or SC, Tofidence IV [off-label], Tyenne IV or SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

Product Name:Actemra SC, Tyenne SC [off-label]	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following [6-8]:

1.1 Exclusion of other known causes of interstitial lung disease (ILD)

AND

1.2 One of the following:

1.2.1 In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD

AND

2 - Prescribed by or in consultation with a pulmonologist or rheumatologist

AND

3 - Both of the following: (Applies to Tyenne SC only)

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

3.2 Submission of medical records documenting why the covered product has not been effective

Product Name:Actemra SC, Tyenne SC [off-label]	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

Product Name:Actemra IV, Tofidence IV [off-label], Tyenne IV [off-label]	
Diagnosis	Coronavirus disease 2019 (COVID-19)

Approval Length	14 Days [B]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand

Approval Criteria

1 - Diagnosis of COVID-19

AND

2 - Patient is hospitalized

AND

3 - Currently receiving systemic corticosteroids

AND

4 - Patient requires one of the following:

Supplemental oxygen

Non-invasive mechanical ventilation

Invasive mechanical ventilation

Extracorporeal membrane oxygenation (ECMO)

AND

5 - Both of the following: (Applies to Tofidence IV and Tyenne IV only)

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of Actemra (tocilizumab)

AND

5.2 Submission of medical records documenting why the covered product has not been effective

Product Name:Actemra IV, Tofidence IV [off-label], Tyenne IV [off-label]	
Diagnosis	Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy
Approval Length	2 Months [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand

Approval Criteria

1 - Patient will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy (e.g., Kymriah [tisagenlecleucel], Yescarta [axicabtagene ciloleucel])

AND

2 - Prescribed by or in consultation with an oncologist or hematologist

AND

3 - Both of the following: (Applies to Tofidence IV and Tyenne IV only)

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of Actemra (tocilizumab)

AND

3.2 Submission of medical records documenting why the covered product has not been effective

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products Adalimumab-adaz Hyrimoz Hadlima Adalimumab-fkjp

4 . Endnotes

Patients should have Actemra on board for initial CAR T-cell therapy and be evaluated for signs and symptoms of CRS for at least 4 weeks after, up to a total of 4 doses of Actemra with at least 8 hours between doses. [1]

The recommended dosage of Actemra for treatment of adult patients with COVID-19 is 8 mg/kg administered as a single 60-minute intravenous infusion. If clinical signs or symptoms worsen or do not improve after the first dose, one additional infusion of Actemra may be administered at least 8 hours after the initial infusion. [1]

5 . References

Actemra Prescribing Information. Genentech, Inc. South San Francisco, CA. December 2022.

Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.

Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.

Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.

Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.

Khanna D, Lin CJF, Furst DE, et al. Tocilizumab in systemic sclerosis: a randomized, double-blind, placebo-controlled, phase 3 trial. Lancet Respir Med. 2020;8:963–74.

Fischer A, Swigris JJ, Groshong SD, et al. Clinically significant interstitial lung disease in limited scleroderma: histopathology, clinical features, and survival. Chest 2008; 134:601.

UptoDate [internet database]. Waltham, MA. UpToDate, Inc. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Available by subscription at: https://www.uptodate.com. Accessed April 11, 2021.

Tofidence Prescribing Information. Biogen MA Inc. Cambridge, MA. September 2023.

Tyenne Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. March 2024.

6 . Revision History

Date	Notes
11/7/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-229008
Guideline Name	Tolvaptan Products - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Samsca (tolvaptan)
Hyponatremia, hypervolemic and euvolemic Indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH). Important limitations: Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Samsca. It has not been established that raising serum sodium with Samsca provides a symptomatic benefit to patients.
Drug Name: Jynarque (tolvaptan)
Autosomal Dominant Polycystic Kidney Disease Indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

2 . Criteria

Product Name:Brand Samsca or Generic tolvaptan	
Approval Length	30 Days [1]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TOLVAPTAN	TOLVAPTAN TAB 15 MG	30454060000320	Generic
SAMSCA	TOLVAPTAN TAB 15 MG	30454060000320	Brand
TOLVAPTAN	TOLVAPTAN TAB 30 MG	30454060000330	Generic
SAMSCA	TOLVAPTAN TAB 30 MG	30454060000330	Brand

Approval Criteria

1 - One of the following:

Diagnosis of significant euvolemic hyponatremia [1-3, A-B]

Diagnosis of significant hypervolemic hyponatremia [1-3, A, C]

AND

2 - Treatment has been initiated or re-initiated in a hospital setting prior to discharge within the past 30 days [1, D]

AND

3 - Trial and failure or intolerance to generic tolvaptan (applies to Brand Samsca only)

Product Name:Jynarque	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JYNARQUE	TOLVAPTAN TAB 15 MG	30454060000320	Brand
JYNARQUE	TOLVAPTAN TAB 30 MG	30454060000330	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 15 MG	3045406000B710	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 30 & 15 MG	3045406000B720	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 45 & 15 MG	3045406000B725	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 60 & 30 MG	3045406000B735	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 90 & 30 MG	3045406000B745	Brand

Approval Criteria

1 - Diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is new to therapy or has received Jynarque for less than or equal to 18 months

AND

2.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

2.2 Both of the following:

2.2.1 Patient has received Jynarque for longer than 18 months

AND

2.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

AND

3 - Patient does not have a history of significant liver impairment or injury, not including uncomplicated polycystic liver disease [E]

Product Name:Jynarque	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JYNARQUE	TOLVAPTAN TAB 15 MG	30454060000320	Brand
JYNARQUE	TOLVAPTAN TAB 30 MG	30454060000330	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 15 MG	3045406000B710	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 30 & 15 MG	3045406000B720	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 45 & 15 MG	3045406000B725	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 60 & 30 MG	3045406000B735	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 90 & 30 MG	3045406000B745	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient does not have signs or symptoms consistent with hepatic injury [E]

OR

2.2 Patient has uncomplicated polycystic liver disease

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

3.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

3.2 Both of the following:

3.2.1 Patient has received Jynarque for longer than 18 months

AND

3.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

Product Name:Jynarque	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

JYNARQUE	TOLVAPTAN TAB 15 MG	30454060000320	Brand
JYNARQUE	TOLVAPTAN TAB 30 MG	30454060000330	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 15 MG	3045406000B710	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 30 & 15 MG	3045406000B720	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 45 & 15 MG	3045406000B725	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 60 & 30 MG	3045406000B735	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 90 & 30 MG	3045406000B745	Brand

Approval Criteria

1 - Diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Both of the following:

2.1.1 Patient is new to therapy or has received Jynarque for less than or equal to 18 months

AND

2.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

2.2 Both of the following:

2.2.1 Patient has received Jynarque for longer than 18 months

AND

2.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

AND

3 - Patient does not have a history of significant liver impairment or injury, not including uncomplicated polycystic liver disease [E]

Product Name:Jynarque	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
JYNARQUE	TOLVAPTAN TAB 15 MG	30454060000320	Brand
JYNARQUE	TOLVAPTAN TAB 30 MG	30454060000330	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 15 MG	3045406000B710	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 30 & 15 MG	3045406000B720	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 45 & 15 MG	3045406000B725	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 60 & 30 MG	3045406000B735	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 90 & 30 MG	3045406000B745	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient does not have signs or symptoms consistent with hepatic injury [E]

OR

2.2 Patient has uncomplicated polycystic liver disease

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Both of the following:

3.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

3.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

3.2 Both of the following:

3.2.1 Patient has received Jynarque for longer than 18 months

AND

3.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

3 . Endnotes

Normal extracellular fluid volume and osmolality are maintained when the serum sodium concentration is regulated within a narrow range (136 to 148 mEq/L). [2] Hypotonic hyponatremia, a disorder of impaired water excretion rather than salt depletion, results from the kidneys' inability to excrete enough free water to offset water intake. [2] Hypotonic hyponatremia is classified based on the patient's extracellular fluid (ECF) volume status as hypovolemic hyponatremia, euvolemic hyponatremia, or hypervolemic hyponatremia. [3] Samsca is indicated for the treatment of clinically significant euvolemic and hypervolemic hyponatremia, defined as a serum sodium of less than 125 mEq/L or

less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction. [1]

Many different hypo-osmolar disorders can potentially present clinically with a normal ECF volume, or euvolemia, in part because it is difficult to detect modest changes in volume status using standard methods of clinical assessment. [3] Most patients with hyponatremia have clinical euvolemia (most commonly associated with the syndrome of inappropriate secretion of antidiuretic hormone [SIADH] or due to other causes [e.g., hypothyroidism, adrenal insufficiency, other disorders of excess water intake]) and are generally diagnosed clinically from the history, physical examination, and laboratory results. [2-3] Patients without clinical signs of volume depletion (e.g., orthostatic decreases in blood pressure and increases in pulse rate, dry mucus membranes, decreased skin turgor) or volume expansion (e.g., subcutaneous edema, ascites) should be considered to have euvolemia unless there is alternative evidence suggesting an abnormal ECF volume status. [3] Supportive laboratory results include a normal or low blood urea nitrogen (BUN) and a low serum uric acid level. [3] A spot urine sodium concentration should be greater than or equal to 30 mmol/L in most patients with euvolemic hyponatremia unless they have become secondarily sodium depleted. [3]

The presence of clinically detectable increased ECF volume generally reflects hypervolemia from some degree of body sodium excess. [3] Hyponatremia with ECF volume excess can arise in a variety of diseases (e.g., congestive heart failure, cirrhosis, renal failure). [3] Because intravascular volume cannot be easily measured directly, volume excess is generally diagnosed clinically from the history, physical examination, and laboratory results. [3] Patients with clinical signs of volume overload (e.g., subcutaneous edema, ascites, pulmonary edema) should be considered to have hypervolemia unless there are alternative explanations for these findings. [3] Elevation of plasma levels of brain natriuretic peptide (BNP) provides useful laboratory support for the presence of volume overload. [3] The urine sodium, or fractional sodium excretion, is usually low (spot urine sodium of less than 30 mmol/L) in patients with hypervolemic hyponatremia due to activation of the renin-angiotensin-aldosterone system (RAAS) with secondary renal sodium conservation despite the whole-body volume overload. [3]

Because of the risk of osmotic demyelination associated with overly-rapid correction of serum sodium, tolvaptan should be initiated in a hospital so that the serum sodium concentration can be monitored easily. If therapy is discontinued for any reason and the patient becomes hyponatremic, tolvaptan should be re-initiated in a hospital if further treatment with tolvaptan is indicated. "In a hospital" means anywhere in a hospital where the patient can be observed and serum sodium levels can be obtained (e.g., an emergency department, an observation unit, or an inpatient bed). [1]

Jynarque can cause serious and potentially fatal liver injury. Acute liver failure requiring liver transplantation has been reported in the post-marketing ADPKD experience. Discontinuation in response to laboratory abnormalities or signs or symptoms of liver injury (such as fatigue, anorexia, nausea, right upper abdominal discomfort, vomiting, fever, rash, pruritus, icterus, dark urine or jaundice) can reduce the risk of severe hepatotoxicity. ALT, AST and bilirubin should be monitored prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for 18 months and every 3 months thereafter. [4]

4 . References

Samsca Prescribing Information. Otsuka America Pharmaceuticals, Inc. Rockville, MD. April 2021.

Ghali JK. Mechanisms, risks, and new treatment options for hyponatremia. Cardiology. 2008;11:147-157.

Verbalis JG, Goldsmith SR, Greenberg A, et al. Diagnosis, evaluation, and treatment of hyponatremia: expert panel recommendations. The American Journal of Medicine. 2013;126(10 Suppl 1):S1-42.

Jynarque Prescribing Information. Otsuka America Pharmaceuticals, Inc. Rockville, MD. October 2020.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233448
Guideline Name	Topical Acne Treatments - PA, ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Benzaclin (clindamycin phosphate and benzoyl peroxide gel), Benzamycin (erthyromycin and benzoyl peroxide gel)
Acne vulgaris Indicated for the treatment of acne vulgaris.
Drug Name: Acanya (clindamycin phosphate and benzoyl peroxide gel), Veltin (clindamycin phosphate and tretinoin gel), Ziana (clindamycin phosphate and tretinoin gel)
Acne vulgaris Indicated for treatment of acne vulgaris in patients 12 years and older.
Drug Name: Clindagel (clindamycin)
Acne vulgaris Indicated for topical application in the treatment of acne vulgaris.
Drug Name: Onexton (clindamycin phosphate and benzoyl peroxide gel)
Acne vulgaris Indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

2 . Criteria

Product Name:Brand Acanya, Brand Benzaclin, Brand Benzamycin, Brand Veltin, Brand Ziana	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
BENZAMYCIN	BENZOYL PEROXIDE-ERYTHROMYCIN GEL 5-3%	90059902104010	Brand
ACANYA	CLINDAMYCIN PHOSPHATE-BENZOYL PEROXIDE GEL 1.2-2.5%	90059902194030	Brand
VELTIN	CLINDAMYCIN PHOSPHATE-TRETINOIN GEL 1.2-0.025%	90059902654020	Brand
ZIANA	CLINDAMYCIN PHOSPHATE-TRETINOIN GEL 1.2-0.025%	90059902654020	Brand
BENZACLIN	CLINDAMYCIN PHOSPHATE-BENZOYL PEROXIDE GEL 1-5%	90059902194020	Brand
BENZACLIN WITH PUMP	CLINDAMYCIN PHOSPHATE-BENZOYL PEROXIDE GEL 1-5%	90059902194020	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - History of failure (of a minimum 30-day trial), contraindication, or intolerance within the past 180 days to any one of the following:

Epiduo Forte

Onexton^ (clindamycin phosphate/benzoyl peroxide gel 1.2-3.75%)

Twyneo

Notes	^ Brand product may be excluded, please consult client-specific resou rces to confirm formulary coverage.

Product Name:Brand Clindagel, Brand Clindamycin Phosphate	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
CLINDAGEL	CLINDAMYCIN PHOSPHATE GEL 1% (ONCE-DAILY)	90051010104006	Brand
CLINDAMYCIN PHOSPHATE	CLINDAMYCIN PHOSPHATE GEL 1% (ONCE-DAILY)	90051010104006	Generic
CLINDAMYCIN PHOSPHATE	CLINDAMYCIN PHOSPHATE GEL 1% (TWICE-DAILY)	90051010104007	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - History of failure (of a minimum 30-day trial) or intolerance to two generic single-agent topical clindamycin products within the past 180 days

Product Name:Brand Onexton	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ONEXTON	CLINDAMYCIN PHOSPHATE-BENZOYL PEROXIDE GEL 1.2-3.75%	90059902194040	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - History of failure (of a minimum 30-day trial), contraindication, or intolerance within the past 180 days to any one of the following:

Epiduo Forte

Twyneo

Clindamycin/benzoyl peroxide gel 1.2/3.75%

Product Name:Generic clindamycin phosphate/benzoyl peroxide gel 1.2-3.75%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization, Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CLINDAMYCIN PHOSPHATE/BENZOYL PEROXIDE	CLINDAMYCIN PHOSPHATE-BENZOYL PEROXIDE GEL 1.2-3.75%	90059902194040	Generic

Approval Criteria

1 - One of the following:

1.1 Requested drug is FDA-approved for the condition being treated

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming at least 6 months of use of brand Onexton within the previous 365 days

AND

3 - Justification provided for why the generic is expected to provide benefit when brand Onexton has not been shown to be effective

3 . References

Acanya Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2020.

Benzaclin Prescribing Information. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ. February 2017.

Benzamycin Prescribing Information. Bausch Health US LLC. Bridgewater, NJ. November 2020.

Clindagel Prescribing Information. Valeant Pharmaceuticals North America LLC; San Antonio, TX. January 2020.

Veltin Prescribing Information. Almirall, LLC. Exton, PA. August 2021.

Ziana Prescribing Information. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ. March 2017.

4 . Revision History

Date	Notes
3/28/2025	Added new clindamycin GPI(s)

Prior Authorization Guideline

Guideline ID	GL-229011
Guideline Name	Topical Antifungals - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ciclopirox Kit (ciclopirox)
Onychomycosis Indicated as topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement, due to Trichophyton rubrum. The comprehensive management program includes removal of the unattached, infected nails as frequently as monthly, by a health care professional who has special competence in the diagnosis and treatment of nail disorders, including minor nail procedures.
Drug Name: Jublia (efinaconazole) topical solution
Onychomycosis of the toenails Indicated for the topical treatment of onychomycosis of the toenail(s) due to Trichophyton rubrum and Trichophyton mentagrophytes.
Drug Name: Kerydin (tavaborole) topical solution
Onychomycosis of the toenails Indicated for the treatment of onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes.

2 . Criteria

Product Name:Ciclopirox Kit	
Diagnosis	Fingernail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CICLOPIROX TREATMENT	CICLOPIROX SOLUTION KIT 8%	90150030006420	Generic

Approval Criteria

1 - Diagnosis of onychomycosis of the fingernail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of fingernail onychomycosis has been confirmed by one of the following:

Positive potassium hydroxide (KOH) preparation

Culture

Histology

AND

4 - Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine [B]

Product Name:Ciclopirox Kit, Generic tavaborole, Jublia	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JUBLIA	EFINACONAZOLE SOLN 10%	90154037002020	Brand
CICLOPIROX TREATMENT	CICLOPIROX SOLUTION KIT 8%	90150030006420	Generic
TAVABOROLE	TAVABOROLE SOLN 5%	90156080002010	Generic

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

Positive potassium hydroxide (KOH) preparation

Culture

Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Trial and failure, contraindication (of a minimum 12-week supply), or intolerance to oral terbinafine [B]

Product Name:Brand Kerydin	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KERYDIN	TAVABOROLE SOLN 5%	90156080002010	Brand

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

Positive potassium hydroxide (KOH) preparation

Culture

Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Both of the following:

5.1 Trial and failure, contraindication (of a minimum 12-week supply), or intolerance to oral terbinafine [B]

AND

5.2 Trial and failure (of a minimum 48-week supply), contraindication, or intolerance to generic tavaborole

Product Name:Jublia	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
JUBLIA	EFINACONAZOLE SOLN 10%	90154037002020	Brand

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

Positive potassium hydroxide (KOH) preparation

Culture

Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Treatment is requested due to a documented medical condition and not for cosmetic purposes (e.g. patients with history of cellulitis of the lower extremity, patients with diabetes who have additional risk factors for cellulitis of lower extremity, patients who experience pain/discomfort associated with the infected nail)

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to 12 weeks of treatment with ciclopirox

OR

6.2 Patient is 6 to 12 years of age

AND

7 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to 12 weeks of treatment with ONE of the following oral antifungal agents:

itraconazole

terbinafine

griseofulvin

3 . Endnotes

Considering that toenails can take 12 to 18 months to grow out, many clinicians consider that 1 year is too short to assess clinical effectiveness. [4] Reports of long-term follow-up of treated patients have been presented, suggesting that positive mycology at 12 and 24 weeks after commencement of therapy are poor prognostic signs and may indicate a need for retreatment or for a change of drug. [5]

Oral terbinafine has been shown to have superior efficacy compared to topical treatments and is recommended as first-line therapy for onychomycosis. [4, 6, 7] Compared to itraconazole, terbinafine has been found to have lower long-term mycological recurrence rates and better tolerability. [4, 6]

4 . References

Jublia prescribing information. Bausch Health Companies Inc. Bridgewater, NJ. March 2022.

Kerydin prescribing information. PharmaDerm, a division of Fougera Pharmaceuticals, Inc. Melville, NY. August 2018.

Sigurgeirsson B, Olafsson JH, Steinsson JP, et al. Long-term effectiveness of treatment with terbinafine vs. itraconazole in onychomycosis: a 5-year blinded prospective follow-up study. Arch Dermatol. 2002;138:353-7.

Roberts DT, Taylor WD, Boyle J. Guidelines for treatment of onychomycosis. Br J Dermatol. 2003;148:402-410.

Ameen M, Lear JT, Madan V, Mohd Mustapa MF, Richardson M. British Association of Dermatologists' guideline for the management of onychomycosis 2014. Br J Dermatol. 2014;171(5):937-58.

Gupta, AK, Daigle D, Paquet M. Therapies for onychomycosis a systematic review and network meta-analysis of mycological cure. J Am Podiatr Med Assoc. 2015;105(4):357-66.

Gupta AK, Daigle D, Foley KA. Topical therapy for toenail onychomycosis: an evidence-based review. Am J Clin Dermatol. 2014;15:489.

Tavaborole prescribing information. Alembic Pharmaceuticals, Inc. Bridgewater, NJ. November 2021.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229015
Guideline Name	Topical Immunomodulators
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Elidel (pimecrolimus)
Mild to Moderate Atopic Dermatitis Indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.
Drug Name: Protopic (tacrolimus)
Moderate to Severe Atopic Dermatitis Indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

2 . Criteria

Product Name:Brand Elidel cream, generic pimecrolimus cream, Brand Protopic ointment	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ELIDEL	PIMECROLIMUS CREAM 1%	90784060003720	Brand
PIMECROLIMUS	PIMECROLIMUS CREAM 1%	90784060003720	Generic
PROTOPIC	TACROLIMUS OINT 0.03%	90784075004210	Brand
PROTOPIC	TACROLIMUS OINT 0.1%	90784075004230	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance of generic tacrolimus ointment

3 . References

Elidel Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2020.

Protopic Prescribing Information. LEO Pharma Inc. Madison, NJ. June 2022.

Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023 Jul;89(1):e1-e20. doi: 10.1016/j.jaad.2022.12.029. Epub 2023 Jan 12. PMID: 36641009.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228560
Guideline Name	Topical Retinoid Agents
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Atralin (tretinoin), Avita (tretinoin) cream and gel, Retin-A (tretinoin) cream and gel, Retin-A Micro (tretinoin) gel
Acne vulgaris Indicated for the topical treatment of acne vulgaris. **Off Label Uses: Wound healing (mild) [9]** Tretinoin 0.05% cream has been shown to decrease would healing time in patients receiving electroepilation. Enhanced healing of epidermal wounds in patients undergoing dermabrasion when pretreated with tretinoin 0.05% cream has been reported. DRUGDEX Recommendation: Adult, Class IIb, Evidence favors efficacy. **Actinic keratosis [9]** **Hyperkeratosis [9]** **Keloid scar [9]**
Drug Name: Aklief (trifarotene) cream, Arazlo (tazarotene) lotion

Acne vulgaris Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Drug Name: Altreno (tretinoin) lotion

Acne vulgaris Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Off Label Uses: Wound healing (mild) [9] Tretinoin 0.05% cream has been shown to decrease would healing time in patients receiving electroepilation. Enhanced healing of epidermal wounds in patients undergoing dermabrasion when pretreated with tretinoin 0.05% cream has been reported. DRUGDEX Recommendation: Adult, Class IIb, Evidence favors efficacy.

Actinic keratosis [9]

Hyperkeratosis [9]

Keloid scar [9]

Drug Name: Differin (adapalene) cream/lotion/gel/solution/pads

Acne vulgaris Indicated for the topical treatment of acne vulgaris.

Drug Name: Tazorac (tazarotene) cream 0.1%

Acne Vulgaris Indicated for the topical treatment of patients with acne vulgaris.

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis.

Drug Name: Tazorac (tazarotene) cream 0.05%

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis.

Drug Name: Tazorac (tazarotene) gel 0.1%

Acne Vulgaris Indicated for the topical treatment of patients with facial acne vulgaris of mild to moderate severity.

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement.

Drug Name: Tazorac (tazarotene) gel 0.05%

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement.

Drug Name: Fabior (tazarotene) foam

Acne Vulgaris Indicated for the topical treatment of acne vulgaris in patients 12 years of age or older.

2 . Criteria

Product Name:Avita, Brand Retin A Micro (0.06%, 0.08%)	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.08%	90050030204020	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.06%	90050030204017	Brand
AVITA	TRETINOIN CREAM 0.025%	90050030003703	Generic
AVITA	TRETINOIN GEL 0.025%	90050030004010	Generic

Approval Criteria

1 - One of the following:

1.1 Patient is 25 years of age or younger

OR

1.2 Both of the following:

Patient is older than 25 years of age

Diagnosis of acne vulgaris (i.e., acne)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name:Avita, Brand Retin A Micro (0.06%, 0.08%)	
Diagnosis	Other Medical Uses (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.08%	90050030204020	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.06%	90050030204017	Brand
AVITA	TRETINOIN CREAM 0.025%	90050030003703	Generic
AVITA	TRETINOIN GEL 0.025%	90050030004010	Generic

Approval Criteria

1 - One of the following diagnoses: [A, 9]

Actinic keratosis

Hyperkeratosis

Keloid scar

Wound healing (mild)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name:Aklief	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AKLIEF	TRIFAROTENE CREAM 0.005%	90050035003720	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one of the following generics:

Adapalene (cream, gel)

Topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one of the following generics:

Adapalene (cream, gel)

Topical tretinoin or tretinoin microsphere

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name:Altreno, Atralin, Brand Retin-A, Brand Retin-A Micro (0.1% 0.04%), Brand Adapalene 0.1% Soln, Brand Adapalene 0.1% Pads	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETIN-A	TRETINOIN CREAM 0.025%	90050030003703	Brand
RETIN-A	TRETINOIN CREAM 0.05%	90050030003705	Brand
RETIN-A	TRETINOIN CREAM 0.1%	90050030003710	Brand
RETIN-A	TRETINOIN GEL 0.01%	90050030004005	Brand
RETIN-A	TRETINOIN GEL 0.025%	90050030004010	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.04%	90050030204015	Brand
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.04%	90050030204015	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.1%	90050030204030	Brand
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.1%	90050030204030	Brand
ATRALIN	TRETINOIN GEL 0.05%	90050030004015	Brand
ALTRENO	TRETINOIN LOTION 0.05%	90050030004130	Brand
ADAPALENE	ADAPALENE SOLN 0.1%	90050003002010	Brand
ADAPALENE	ADAPALENE PADS 0.1%	90050003004310	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

Adapalene (cream, gel)

Topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

Adapalene (cream, gel)

Topical tretinoin or tretinoin microsphere

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name:Altreno, Atralin, Brand Retin-A, Brand Retin-A Micro (0.04%, 0.1%)	
Diagnosis	Other Medical Uses (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETIN-A	TRETINOIN CREAM 0.025%	90050030003703	Brand
RETIN-A	TRETINOIN CREAM 0.05%	90050030003705	Brand
RETIN-A	TRETINOIN CREAM 0.1%	90050030003710	Brand
RETIN-A	TRETINOIN GEL 0.01%	90050030004005	Brand
RETIN-A	TRETINOIN GEL 0.025%	90050030004010	Brand
ALTRENO	TRETINOIN LOTION 0.05%	90050030004130	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.04%	90050030204015	Brand
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.04%	90050030204015	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.1%	90050030204030	Brand
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.1%	90050030204030	Brand
ATRALIN	TRETINOIN GEL 0.05%	90050030004015	Brand

Approval Criteria

1 - One of the following diagnoses: [A, 9]

Actinic keratosis

Hyperkeratosis

Keloid Scar

Wound healing (mild)

AND

2 - Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to any generic topical tretinoin product	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name:Brand Differin	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIFFERIN	ADAPALENE CREAM 0.1%	90050003003710	Brand
DIFFERIN	ADAPALENE GEL 0.1%	90050003004010	Brand
DIFFERIN	ADAPALENE GEL 0.3%	90050003004030	Brand
DIFFERIN	ADAPALENE LOTION 0.1%	90050003004110	Generic

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

adapalene (cream, gel)

Topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

adapalene (cream, gel)

Topical tretinoin or tretinoin microsphere

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name:Arazlo, Fabior, Brand Tazarotene 0.1% foam, Brand Tazorac 0.1% cream and gel	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZORAC	TAZAROTENE CREAM 0.1%	90250070003730	Brand
TAZORAC	TAZAROTENE GEL 0.1%	90250070004030	Brand
FABIOR	TAZAROTENE (ACNE) FOAM 0.1%	90050027003930	Brand
ARAZLO	TAZAROTENE (ACNE) LOTION 0.045%	90050027004120	Brand
TAZAROTENE	TAZAROTENE (ACNE) FOAM 0.1%	90050027003930	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication or intolerance to BOTH of the following:

1.1.2.1 generic tazarotene

AND

1.1.2.2 One of the following:

generic adapalene

generic topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication or intolerance to BOTH of the following:

1.2.3.1 generic tazarotene

AND

1.2.3.2 One of the following:

generic adapalene

generic topical tretinoin or tretinoin microsphere

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name:Brand Tazorac	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZORAC	TAZAROTENE CREAM 0.05%	90250070003720	Brand
TAZORAC	TAZAROTENE CREAM 0.1%	90250070003730	Brand
TAZORAC	TAZAROTENE GEL 0.05%	90250070004020	Brand
TAZORAC	TAZAROTENE GEL 0.1%	90250070004030	Brand

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Both of the following:

2.1 Trial and failure (of a minimum 30-day supply) within the past 180 days, or intolerance to generic tazarotene

AND

2.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one medium to high potency topical corticosteroid (e.g., triamcinolone, fluocinonide)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name:Generic tazarotene 0.1% cream, Generic tazarotene 0.05% cream, generic tazarotene 0.1% gel, generic tazarotene 0.05% gel	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZAROTENE	TAZAROTENE CREAM 0.1%	90250070003730	Generic
TAZAROTENE	TAZAROTENE GEL 0.05%	90250070004020	Generic
TAZAROTENE	TAZAROTENE GEL 0.1%	90250070004030	Generic
TAZAROTENE	TAZAROTENE CREAM 0.05%	90250070003720	Generic

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one medium to high potency topical corticosteroid (e.g., triamcinolone, fluocinonide)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name:Generic tazarotene 0.1% cream, generic tazarotene 0.1% gel	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZAROTENE	TAZAROTENE CREAM 0.1%	90250070003730	Generic
TAZAROTENE	TAZAROTENE GEL 0.1%	90250070004030	Generic

Approval Criteria

1 - One of the following:

1.1 Patient is 25 years of age or younger

OR

1.2 Both of the following:

Patient is older than 25 years of age

Diagnosis of acne vulgaris (i.e., acne)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

3 . Background

Clinical Practice Guidelines

Table 1. The use of topical retinoids for the following conditions was clarified as either medical or cosmetic (plan exclusions) [10]

Uses	Medical vs. Cosmetic

Actinic keratosis	Medical
Alopecia areata	Medical
Chloasma	Cosmetic
Fine wrinkles on face	Cosmetic
Hyperkeratosis	Medical
Hyperpigmentation of skin, Facial mottling	Cosmetic
Keloid scar	Medical
Roughness of skin, Facial tactile roughness	Cosmetic
Systematized epidermal nevus	Medical
Ultraviolet-induced change in normal skin	Cosmetic
Wound healing (mild)	Medical

Table 2. Relative potencies of topical corticosteroids [14-15]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1

	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

The use of topical retinoids for the following conditions was clarified as either medical or cosmetic (plan exclusions). [10] Please refer to Background section for table with details.

5 . References

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Prior Authorization Guideline

Guideline ID	GL-228561
Guideline Name	Topical Rosacea Agents
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zilxi (minocycline) foam, Epsolay (benzoyl peroxide) cream
Rosacea Indicated for the treatment of inflammatory lesions of rosacea in adults.
Drug Name: Finacea (azelaic acid) gel
Rosacea Indicated for topical treatment of the inflammatory papules and pustules of mild to moderate rosacea. Efficacy for treatment of erythema in rosacea in the absence of papules and pustules has not been evaluated.
Drug Name: Noritate (metronidazole) cream
Rosacea Indicated for the topical treatment of inflammatory lesions and erythema of rosacea.
Drug Name: Metrogel (metronidazole) gel
Rosacea Indicated for the topical treatment of inflammatory lesions of rosacea.
Drug Name: Rhofade (oxymetazoline hydrochloride) cream

Rosacea Indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

2 . Criteria

Product Name:Epsolay Cream, Brand Finacea Gel, Zilxi Foam, Noritate Cream	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ZILXI	MINOCYCLINE HCL MICRONIZED FOAM 1.5%	90060044123920	Brand
FINACEA	AZELAIC ACID GEL 15%	90060010004020	Brand
NORITATE	METRONIDAZOLE CREAM 1%	90060040003720	Brand
EPSOLAY	BENZOYL PEROXIDE CREAM 5%	90050010003710	Brand

Approval Criteria

1 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance to one of the following:

azelaic acid gel

Soolantra cream

Finacea foam

Product Name:Brand Metrogel	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
METROGEL	METRONIDAZOLE GEL 1%	90060040004020	Brand

Approval Criteria

1 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance to one of the following:

generic metronidazole gel

Soolantra cream

Finacea foam

Product Name:Rhofade	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
RHOFADE	OXYMETAZOLINE HCL CREAM 1%	90060050103720	Brand

Approval Criteria

1 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance to Mirvaso (brimonidine gel)

3 . References

Zilxi Prescribing Information. Vyne Pharmaceuticals Inc. Bridgewater, NJ. September 2022.

Finacea Gel Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. November 2021.

Noritate Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. June 2020.

Metrogel Prescribing Information. Galderma Laboratories, L.P. Fort Worth, TX. November 2023.

Epsolay Prescribing Information. Galderma Laboratories, LP. Fort Worth, TX. April 2023.

Rhofade Prescribing Information. Allergan, Inc. Irvine, CA. November 2018.

Prior Authorization Guideline

Guideline ID	GL-233381
Guideline Name	Trastuzumab - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	9/8/2000
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Herceptin (trastuzumab), Hercessi (trastuzumab-strf), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dkst), Trazimera (trastuzumab-qyyp)
Adjuvant Breast Cancer Indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: 1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, 2) with docetaxel and carboplatin, 3) as a single agent following multi-modality anthracycline based therapy. **Metastatic Breast Cancer** Indicated: 1) In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, 2) As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease. **Metastatic Gastric Cancer** Indicated in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2 overexpressing metastatic gastric or

gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease.

Drug Name: Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)

Adjuvant Breast Cancer Indicated for adjuvant treatment of adults with HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: 1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, 2) as part of a treatment regimen with docetaxel and carboplatin, 3) as a single agent following multi-modality anthracycline based therapy.

Metastatic Breast Cancer Indicated in adults: 1) In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, 2) As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.

2 . Criteria

Product Name:Kanjinti, Trazimera	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KANJINTI	TRASTUZUMAB-ANNS FOR IV SOLN 150 MG	21170070142110	Brand
KANJINTI	TRASTUZUMAB-ANNS FOR IV SOLN 420 MG	21170070142121	Brand
TRAZIMERA	TRASTUZUMAB-QYYP FOR IV SOLN 150 MG	21170070652110	Brand
TRAZIMERA	TRASTUZUMAB-QYYP FOR IV SOLN 420 MG	21170070652120	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

Adjuvant treatment

Used in combination with Perjeta (pertuzumab)

Product Name:Kanjinti, Trazimera	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KANJINTI	TRASTUZUMAB-ANNS FOR IV SOLN 150 MG	21170070142110	Brand
KANJINTI	TRASTUZUMAB-ANNS FOR IV SOLN 420 MG	21170070142121	Brand
TRAZIMERA	TRASTUZUMAB-QYYP FOR IV SOLN 150 MG	21170070652110	Brand
TRAZIMERA	TRASTUZUMAB-QYYP FOR IV SOLN 420 MG	21170070652120	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [3-5, 7, C]

Used in combination with a taxane

Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

Used in combination with Perjeta (pertuzumab)

Product Name:Kanjinti, Trazimera	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KANJINTI	TRASTUZUMAB-ANNS FOR IV SOLN 150 MG	21170070142110	Brand
KANJINTI	TRASTUZUMAB-ANNS FOR IV SOLN 420 MG	21170070142121	Brand
TRAZIMERA	TRASTUZUMAB-QYYP FOR IV SOLN 150 MG	21170070652110	Brand
TRAZIMERA	TRASTUZUMAB-QYYP FOR IV SOLN 420 MG	21170070652120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Kanjinti, Trazimera	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KANJINTI	TRASTUZUMAB-ANNS FOR IV SOLN 150 MG	21170070142110	Brand
KANJINTI	TRASTUZUMAB-ANNS FOR IV SOLN 420 MG	21170070142121	Brand
TRAZIMERA	TRASTUZUMAB-QYYP FOR IV SOLN 150 MG	21170070652110	Brand
TRAZIMERA	TRASTUZUMAB-QYYP FOR IV SOLN 420 MG	21170070652120	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [3-5, 7, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [3-5, 7, C]

Platinol (cisplatin) and Adrucil (5-fluorouracil)

Platinol (cisplatin) and Xeloda (capecitabine)

Product Name:Kanjinti, Trazimera	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KANJINTI	TRASTUZUMAB-ANNS FOR IV SOLN 150 MG	21170070142110	Brand
KANJINTI	TRASTUZUMAB-ANNS FOR IV SOLN 420 MG	21170070142121	Brand
TRAZIMERA	TRASTUZUMAB-QYYP FOR IV SOLN 150 MG	21170070652110	Brand
TRAZIMERA	TRASTUZUMAB-QYYP FOR IV SOLN 420 MG	21170070652120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Herceptin Hylecta	
Diagnosis	Adjuvant Breast Cancer

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HERCEPTIN HYLECTA	TRASTUZUMAB-HYALURONIDASE-OYSK INJ 600-10000 MG-UNIT/5ML	21990002722020	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing breast cancer [A]

AND

2 - One of the following:

2.1 Administered as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel

OR

2.2 Administered as part of a treatment regimen with docetaxel and carboplatin

OR

2.3 Administered as a single agent following multi-modality anthracycline based therapy

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herceptin Hylecta	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HERCEPTIN HYLECTA	TRASTUZUMAB-HYALURONIDASE-OYSK INJ 600-10000 MG-UNIT/5ML	21990002722020	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following:

3.1 Administered in combination with paclitaxel for first-line treatment

OR

3.2 Administered as a single agent for treatment in patients who have received one or more chemotherapy regimens for metastatic disease

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herceptin Hylecta	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HERCEPTIN HYLECTA	TRASTUZUMAB-HYALURONIDASE-OYSK INJ 600-10000 MG-UNIT/5ML	21990002722020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herceptin, Hercessi, Herzuma, Ogivri, Ontruzant	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HERCEPTIN	TRASTUZUMAB FOR IV SOLN 150 MG	21170070002110	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 150 MG	21170070302108	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 420 MG	21170070302120	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 150 MG	21170070602110	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 420 MG	21170070602120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 150 MG	21170070342120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 420 MG	21170070342140	Brand
HERCESSI	TRASTUZUMAB-STRF FOR IV SOLN 150 MG	21170070402150	Brand
HERCESSI	TRASTUZUMAB-STRF FOR IV SOLN 420 MG	21170070402160	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

Adjuvant treatment

Used in combination with Perjeta (pertuzumab)

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herzuma, Ogivri, Ontruzant	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 150 MG	21170070302108	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 420 MG	21170070302120	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 150 MG	21170070602110	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 420 MG	21170070602120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 150 MG	21170070342120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 420 MG	21170070342140	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

Adjuvant treatment

Used in combination with Perjeta (pertuzumab)

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

Product Name:Herceptin, Hercessi, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HERCEPTIN	TRASTUZUMAB FOR IV SOLN 150 MG	21170070002110	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 150 MG	21170070302108	Brand

OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 420 MG	21170070302120	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 150 MG	21170070602110	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 420 MG	21170070602120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 150 MG	21170070342120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 420 MG	21170070342140	Brand
HERCESSI	TRASTUZUMAB-STRF FOR IV SOLN 150 MG	21170070402150	Brand
HERCESSI	TRASTUZUMAB-STRF FOR IV SOLN 420 MG	21170070402160	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [1, 4-6, 8-9, C]

Used in combination with a taxane

Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

Used in combination with Perjeta (pertuzumab)

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herceptin, Hercessi, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HERCEPTIN	TRASTUZUMAB FOR IV SOLN 150 MG	21170070002110	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 150 MG	21170070302108	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 420 MG	21170070302120	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 150 MG	21170070602110	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 420 MG	21170070602120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 150 MG	21170070342120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 420 MG	21170070342140	Brand
HERCESSI	TRASTUZUMAB-STRF FOR IV SOLN 150 MG	21170070402150	Brand
HERCESSI	TRASTUZUMAB-STRF FOR IV SOLN 420 MG	21170070402160	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 150 MG	21170070302108	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 420 MG	21170070302120	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 150 MG	21170070602110	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 420 MG	21170070602120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 150 MG	21170070342120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 420 MG	21170070342140	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [1, 4-6, 8-9, C]

Used in combination with a taxane

Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

Used in combination with Perjeta (pertuzumab)

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

Product Name:Herceptin, Hercessi, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HERCEPTIN	TRASTUZUMAB FOR IV SOLN 150 MG	21170070002110	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 150 MG	21170070302108	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 420 MG	21170070302120	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 150 MG	21170070602110	Brand

HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 420 MG	21170070602120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 150 MG	21170070342120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 420 MG	21170070342140	Brand
HERCESSI	TRASTUZUMAB-STRF FOR IV SOLN 150 MG	21170070402150	Brand
HERCESSI	TRASTUZUMAB-STRF FOR IV SOLN 420 MG	21170070402160	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [1, 4-6, 8-9, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [1, 4-6, 8-9, C]

Platinol (cisplatin) and Adrucil (5-fluorouracil)

Platinol (cisplatin) and Xeloda (capecitabine)

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herceptin, Hercessi, Herzuma, Ogivri, Ontruzantt	
Diagnosis	Metastatic Gastric Cancer

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HERCEPTIN	TRASTUZUMAB FOR IV SOLN 150 MG	21170070002110	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 150 MG	21170070302108	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 420 MG	21170070302120	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 150 MG	21170070602110	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 420 MG	21170070602120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 150 MG	21170070342120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 420 MG	21170070342140	Brand
HERCESSI	TRASTUZUMAB-STRF FOR IV SOLN 150 MG	21170070402150	Brand
HERCESSI	TRASTUZUMAB-STRF FOR IV SOLN 420 MG	21170070402160	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 150 MG	21170070302108	Brand
OGIVRI	TRASTUZUMAB-DKST FOR IV SOLN 420 MG	21170070302120	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 150 MG	21170070602110	Brand
HERZUMA	TRASTUZUMAB-PKRB FOR IV SOLN 420 MG	21170070602120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 150 MG	21170070342120	Brand
ONTRUZANT	TRASTUZUMAB-DTTB FOR IV SOLN 420 MG	21170070342140	Brand

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [1, 4-6, 8-9, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [1, 4-6, 8-9, C]

Platinol (cisplatin) and Adrucil (5-fluorouracil)

Platinol (cisplatin) and Xeloda (capecitabine)

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

3 . Endnotes

Detection of HER2 protein overexpression is necessary for selection of patients appropriate for trastuzumab therapy because these are the only patients studied and for whom benefit has been shown. Due to differences in tumor histopathology, use FDA-approved tests for the specific tumor type (e.g. breast or gastric/gastroesophageal adenocarcinoma) to assess HER2 protein overexpression and HER2 gene amplification. Assessment of HER2 protein overexpression and HER2 gene amplification should be performed using FDA-approved tests specific for breast cancer by laboratories with demonstrated proficiency. Improper assay performance, including use of suboptimally fixed tissue, failure to utilize specified reagents, deviation from specific assay instructions, and failure to include appropriate controls for assay validation, can lead to unreliable results. Assessment of HER2 protein overexpression and HER2 gene amplification in metastatic gastric cancer should be performed using FDA-approved tests specifically for gastric cancers due to differences in gastric vs. breast histopathology, including incomplete membrane staining and more frequent heterogeneous expression of HER2 seen in gastric cancers. Study 7 demonstrated that gene amplification and protein overexpression were not as well correlated as with breast cancer. Treatment outcomes for metastatic gastric cancer (Study 7) are based on HER2 gene amplification (FISH) and HER 2 protein overexpression (IHC) test results. [1-3, 6-9]

Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma and Ontruzant are indicated for the treatment of HER-2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. A pivotal study included patients previously untreated for metastatic gastric or gastroesophageal junction adenocarcinoma. [1, 3, 6-9]

The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [5]

4 . References

Herceptin Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2021.

Herceptin Hylecta Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2019.

Kanjinti Prescribing Information. Amgen Inc. Thousand Oaks, CA. October 2019.

The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available at www.nccn.org. Accessed May 15, 2023.

U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed May 14, 2021.

Ogivri Prescribing Information. Mylan Institutional LLC. Rockford, IL. February 2021.

Trazimera Prescribing Information. Pfizer Laboratories Div Pfizer Inc. New York, NY. November 2020.

Herzuma Prescribing Information. Celltrion, Inc. Incheon, Republic of Korea. May 2019.

Ontruzant Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. March 2020.

Hercessi Prescribing Information. Accord BioPharma Inc.Raleigh, NC. September 2024.

5 . Revision History

Date	Notes
3/13/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-229016
Guideline Name	Tremfya (guselkumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tremfya SC (guselkumab)
Plaque Psoriasis (PsO) Indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis. **Ulcerative Colitis (UC)** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.
Drug Name: Tremfya IV (guselkumab)
Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

2 . Criteria

Product Name:Tremfya SC 100 mg	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand

Approval Criteria

1 - Diagnosis of moderate-to-severe plaque psoriasis

AND

2 - One of the following [2]:

Greater than or equal to 3% body surface area involvement

Severe scalp psoriasis

Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Tremfya SC 100 mg	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Tremfya SC 100 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [4]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Tremfya SC 100 mg	
Diagnosis	Psoriatic Arthritis (PsA)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

Notes	If patient meets criteria above, please approve at GPI-14

Product Name:Tremfya IV	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB IV SOLN 200 MG/20ML (10 MG/ML)	52504025002030	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [5, 6]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein)

Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [5, 6]:

6-mercaptopurine

Azathioprine

Corticosteroid (e.g., prednisone)

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

AND

4 - Will be administered as an intravenous induction dose

AND

5 - Prescribed by or in consultation with a gastroenterologist

Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 200 MG/2ML	5250402500D540	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 200 MG/2ML	5250402500E540	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name:Tremfya SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand

TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 200 MG/2ML	5250402500D540	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 200 MG/2ML	5250402500E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5, 6]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

3 . References

Tremfya Prescribing Information. Janssen Biotech, Inc. Horsham, PA. September 2024.

Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.

Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-233194
Guideline Name	Trikafta (elexacaftor/tezacaftor/ivacaftor)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/14/2019
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Trikafta (elexacaftor/tezacaftor/ivacaftor)
Cystic Fibrosis Indicated for the treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data.

2 . Criteria

Product Name:Trikafta

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRIKAFTA	ELEXACAF-TEZACAF-IVACAF 100-50-75 MG &IVACAFTOR 150 MG TBPK	4530990340B740	Brand
TRIKAFTA	ELEXACAF-TEZACAF-IVACAF 100-50-75 MG &IVACAFTOR 150 MG TBPK	4530990340B740	Brand
TRIKAFTA	ELEXACAF-TEZACAF-IVACAF 50-25-37.5 MG & IVACAFTOR 75 MG TBPK	4530990340B720	Brand
TRIKAFTA	ELEXACAF-TEZACAF-IVACAF 80-40-60 MG& IVACAF 59.5MG THPK GRAN	4530990340B120	Brand
TRIKAFTA	ELEXACAF-TEZACAF-IVACAF 100-50-75 MG& IVACAF 75MG THPK GRAN	4530990340B140	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - One of the following:

For granule packets, patient is at least 2 to less than 6 years of age

For tablets, patient is 6 years of age or older

AND

3 - Patient has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by a FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility:*

F508del mutation

A mutation in the CFTR gene that is responsive based on in vitro data

AND

4 - Prescribed by or in consultation with one of the following:

Pulmonologist

Specialist affiliated with a CF care center

Notes	*Please consult Background section for table of CFTR gene mutations responsive to Trikafta.

Product Name:Trikafta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRIKAFTA	ELEXACAF-TEZACAF-IVACAF 100-50-75 MG &IVACAFTOR 150 MG TBPK	4530990340B740	Brand
TRIKAFTA	ELEXACAF-TEZACAF-IVACAF 100-50-75 MG &IVACAFTOR 150 MG TBPK	4530990340B740	Brand
TRIKAFTA	ELEXACAF-TEZACAF-IVACAF 50-25-37.5 MG & IVACAFTOR 75 MG TBPK	4530990340B720	Brand
TRIKAFTA	ELEXACAF-TEZACAF-IVACAF 80-40-60 MG& IVACAF 59.5MG THPK GRAN	4530990340B120	Brand
TRIKAFTA	ELEXACAF-TEZACAF-IVACAF 100-50-75 MG& IVACAF 75MG THPK GRAN	4530990340B140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations) [1,2]

3 . Background

Clinical Practice Guidelines

CFTR Mutations that are responsive to Trikafta

*Intent of table is to provide a quick reference; PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 11/4/24]

List of *CFTR* Gene Mutations that are Responsive to Trikafta					
3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*
A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C;S1251N* †	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del* *	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*
D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*

D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y;G576A;R668C †	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*
D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*
D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*
E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*
E60K	*G551S*	*K1060T*	*R74W;D1270N* †	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W;V201M* †	*S364P*	*Y161S*
E116K	*G576A;R668C* †	*L165S*	*R74W;V201M;D1270N* †	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

* *F508del* is a responsive *CFTR* mutation based on both clinical and *in vitro* data.

† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent ofthe presence of mutations on the other allele.

4 . References

Trikafta Prescribing information. Vertex Pharmaceuticals Inc. Boston, MA. August 2023.

Keating D, Marigowda G, Burr L, et al. VX-445–tezacaftor–ivacaftor in patients with cystic fibrosis and one or two Phe508del alleles. N Engl J Med. 2018;379:1612-20.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228564
Guideline Name	Trodelvy (sacituzumab govitecan-hziy)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Trodelvy (sacituzumab govitecan-hziy)
Breast Cancer Indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease. **Breast Cancer** Indicated for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting. **Urothelial Cancer** Indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 . Criteria

Product Name:Trodelvy	
Diagnosis	Triple Negative Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRODELVY	SACITUZUMAB GOVITECAN-HZIY FOR IV SOLN 180 MG	21551065402120	Brand

Approval Criteria

1 - Diagnosis of triple negative breast cancer (TNBC) [A]

AND

2 - Disease is one of the following:

Unresectable locally advanced

Metastatic

AND

3 - Patient has received at least two prior therapies for at least one of which is for metastatic disease (e.g., chemotherapy with or without programmed cell death protein-1 (PD-1) inhibitor [e.g., Keytruda (pembrolizumab)], neoadjuvant/adjuvant therapy, poly-ADP ribose polymerase (PARP) inhibitor [e.g., Olaparib, talazoparib], etc.) [1-3]

Product Name:Trodelvy	
Diagnosis	HR-positive, HER2-negative Breast Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRODELVY	SACITUZUMAB GOVITECAN-HZIY FOR IV SOLN 180 MG	21551065402120	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

Unresectable locally advanced

Metastatic

AND

3 - Disease is hormone-receptor (HR) - positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2) - negative

AND

5 - Both of the following:

5.1 Patient has received endocrine-based therapy (e.g., tamoxifen, aromatase inhibitors [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)], fulvestrant)

AND

5.2 Patient has received at least two additional systemic therapies in the metastatic setting (e.g., chemotherapy, poly-ADP ribose polymerase (PARP) inhibitor [e.g., olaparib, talazoparib], fam-trastuzumab deruxtecan-nxki) [B, 3]

Product Name:Trodelvy	
Diagnosis	Urothelial Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRODELVY	SACITUZUMAB GOVITECAN-HZIY FOR IV SOLN 180 MG	21551065402120	Brand

Approval Criteria

1 - Diagnosis of urothelial cancer

AND

2 - Disease is one of the following:

Locally advanced

Metastatic

AND

3 - Patient has previously received both of the following:

3.1 Platinum-containing chemotherapy (e.g., cisplatin, carboplatin)

AND

3.2 One of the following:

Programmed death receptor-1 (PD-1) inhibitor [e.g., Keytruda (pembrolizumab)]

Programmed death-ligand 1 (PD-L1) inhibitor [e.g., Bavencio (avelumab)]

Product Name:Trodelvy	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRODELVY	SACITUZUMAB GOVITECAN-HZIY FOR IV SOLN 180 MG	21551065402120	Brand
TRODELVY	SACITUZUMAB GOVITECAN-HZIY FOR IV SOLN 180 MG	21551065402120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

Triple-negative breast cancer is defined by a lack of tumor-cell expression of the estrogen receptor, progesterone receptor, and human epidermal growth factor receptor 2 (HER2). [2]

Adjuvant or neoadjuvant therapy for early-stage disease will qualify as one of the required prior regimens if the development of unresectable, locally advanced or metastatic disease occurred within 12 months of adjuvant therapy. [1]

4 . References

Trodelvy Prescribing Information. Immunomedics, Inc. Morris Plains, NJ. February 2023.

Bardia A, Mayer IA, Vahdat LT, et al. Sacituzumab govitecan-hziy in refractory metastatic triple-negative breast cancer. N Engl Med. 2019;380:741-51.

The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 23, 2023.

Prior Authorization Guideline

Guideline ID	GL-229161
Guideline Name	Truqap (capivasertib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	1/17/2024
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Truqap (capivasertib)
Breast Cancer Indicated, in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

2 . Criteria

Product Name:Truqap

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRUQAP	CAPIVASERTIB TAB 160 MG	21530320000320	Brand
TRUQAP	CAPIVASERTIB TAB 200 MG	21530320000325	Brand
TRUQAP	CAPIVASERTIB TAB THERAPY PACK 160 MG	2153032000B720	Brand
TRUQAP	CAPIVASERTIB TAB THERAPY PACK 200 MG	2153032000B725	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

Locally advanced

Metastatic

AND

3 - Will be taken in combination with fulvestrant

AND

4 - Disease is hormone receptor (HR)-positive

AND

5 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

6 - Patient has one or more PIK3CA/AKT1/PTEN-alterations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

7 - One of the following:

7.1 Following progression on at least one endocrine-based regimen in the metastatic setting (e.g., anastrozole, letrozole, exemestane, tamoxifen, etc).

OR

7.2 Recurrence on or within 12 months of completing adjuvant therapy (e.g., chemotherapy)

Product Name:Truqap	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRUQAP	CAPIVASERTIB TAB 160 MG	21530320000320	Brand
TRUQAP	CAPIVASERTIB TAB 200 MG	21530320000325	Brand
TRUQAP	CAPIVASERTIB TAB THERAPY PACK 160 MG	2153032000B720	Brand
TRUQAP	CAPIVASERTIB TAB THERAPY PACK 200 MG	2153032000B725	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Truqap Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. November 2023.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228565
Guideline Name	Truseltiq (infigratinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Truseltiq (infigratinib)
Cholangiocarcinoma Indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

2 . Criteria

Product Name:Truseltiq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRUSELTIQ	INFIGRATINIB PHOS CAP THER PACK 2 X 25 MG (50 MG DAILY DOSE)	2153223540B220	Brand
TRUSELTIQ	INFIGRATINIB PHOS CAP THER PACK 3 X 25 MG (75 MG DAILY DOSE)	2153223540B225	Brand
TRUSELTIQ	INFIGRATINIB PHOS CAP THER PACK 100 MG (100 MG DAILY DOSE)	2153223540B230	Brand
TRUSELTIQ	INFIGRATINIB PHOS CAP PACK 100 & 25 MG (125 MG DAILY DOSE)	2153223540B235	Brand

Approval Criteria

1 - Diagnosis of cholangiocarcinoma

AND

2 - Disease is one of the following:

Unresectable locally advanced

Metastatic

AND

3 - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Patient has been previously treated

Product Name:Truseltiq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRUSELTIQ	INFIGRATINIB PHOS CAP THER PACK 2 X 25 MG (50 MG DAILY DOSE)	2153223540B220	Brand
TRUSELTIQ	INFIGRATINIB PHOS CAP THER PACK 3 X 25 MG (75 MG DAILY DOSE)	2153223540B225	Brand
TRUSELTIQ	INFIGRATINIB PHOS CAP THER PACK 100 MG (100 MG DAILY DOSE)	2153223540B230	Brand
TRUSELTIQ	INFIGRATINIB PHOS CAP PACK 100 & 25 MG (125 MG DAILY DOSE)	2153223540B235	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Truseltiq Prescribing Information. QED Therapeutics, Inc. Brisbane, CA. May 2021.

Truvada 200/300 mg (emtricitabine/tenofovir disoproxil fumarate)

Prior Authorization Guideline

Guideline ID	GL-233215
Guideline Name	Truvada 200/300 mg (emtricitabine/tenofovir disoproxil fumarate)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/21/2020
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Truvada (emtricitabine/tenofovir disoproxil fumarate)
Treatment of HIV-1 Infection Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg. **HIV-1 Pre-Exposure Prophylaxis (PrEP)** Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test immediately prior to initiating Truvada for HIV-1 PrEP.

2 . Criteria

Product Name:Brand Truvada 200/300 mg	
Diagnosis	Treatment of HIV Infection
Approval Length	24 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRUVADA	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TAB 200-300 MG	12109902300320	Brand

Approval Criteria

1 - Truvada is being used for the treatment of HIV infection

Product Name:Brand Truvada 200/300 mg	
Diagnosis	HIV Pre-exposure Prophylaxis (PrEP)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRUVADA	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TAB 200-300 MG	12109902300320	Brand

Approval Criteria

1 - Truvada is being used for HIV Pre-exposure Prophylaxis (PrEP)

AND

2 - Patient has a history of intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300 mg

3 . References

Truvada Prescribing Information. Gilead Sciences, Inc. Foster City, CA. April 2024.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-229017
Guideline Name	Tukysa (tucatinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tukysa (tucatinib)
Breast Cancer Indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. **Colorectal cancer** Indicated in combination with trastuzumab for the treatment of adult patients with RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2 . Criteria

Product Name:Tukysa	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TUKYSA	TUCATINIB TAB 50 MG	21170080000320	Brand
TUKYSA	TUCATINIB TAB 150 MG	21170080000340	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

Advanced unresectable

Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Used in combination with trastuzumab and capecitabine

AND

5 - Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine)

Product Name:Tukysa	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TUKYSA	TUCATINIB TAB 50 MG	21170080000320	Brand
TUKYSA	TUCATINIB TAB 150 MG	21170080000340	Brand

Approval Criteria

1 - Diagnosis of colorectal cancer

AND

2 - Disease is one of the following:

Unresectable

Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Patient has RAS wild-type tumors

AND

5 - Used in combination with trastuzumab

AND

6 - Patient has progressed following treatment with ONE of the following:

Fluoropyrimidine-based chemotherapy

Oxaliplatin-based chemotherapy

Irinotecan-based chemotherapy

Product Name:Tukysa	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TUKYSA	TUCATINIB TAB 50 MG	21170080000320	Brand
TUKYSA	TUCATINIB TAB 150 MG	21170080000340	Brand
TUKYSA	TUCATINIB TAB 50 MG	21170080000320	Brand
TUKYSA	TUCATINIB TAB 150 MG	21170080000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Tukysa Prescribing Information. Seattle Genetics, Inc. Bothell, WA. January 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229020
Guideline Name	Turalio (pexidartinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Turalio (pexidartinib)
Tenosynovial Giant Cell Tumor (TGCT) Indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

2 . Criteria

Product Name:Turalio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TURALIO	PEXIDARTINIB HCL CAP 200 MG (BASE EQUIVALENT)	21533045010120	Brand
TURALIO	PEXIDARTINIB HCL CAP 125 MG (BASE EQUIVALENT)	21533045010110	Brand

Approval Criteria

1 - Diagnosis of tenosynovial giant cell tumor (TGCT)

AND

2 - Patient is symptomatic

AND

3 - Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal

Product Name:Turalio	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TURALIO	PEXIDARTINIB HCL CAP 200 MG (BASE EQUIVALENT)	21533045010120	Brand
TURALIO	PEXIDARTINIB HCL CAP 125 MG (BASE EQUIVALENT)	21533045010110	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Turalio prescribing information. Daiichi Sankyo, Inc. Basking Ridge, NJ. November 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229021
Guideline Name	Tykerb (lapatinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tykerb (lapatinib)
Metastatic breast cancer (1) In combination with Xeloda (capecitabine), indicated for the treatment of patients with advanced or metastatic breast cancer whose tumors over-express HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. Limitations of use: Patients should have disease progression on trastuzumab prior to initiation of treatment with Tykerb in combination with capecitabine.; (2) In combination with Femara (letrozole), indicated for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated. Tykerb in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer. **Off Label Uses: HER2-positive Breast Cancer [4-6]** Used for the first-line treatment of HER2-positive locally-advanced or metastatic breast cancer.

2 . Criteria

Product Name:Brand Tykerb, generic lapatinib	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LAPATINIB DITOSYLATE	LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)	21533026100320	Generic
TYKERB	LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)	21533026100320	Brand

Approval Criteria

1 - Diagnosis of HER2-positive metastatic or recurrent breast cancer [2-6]

AND

2 - Used in combination with one of the following: [3]

Trastuzumab

Xeloda (capecitabine)

Aromatase inhibitors [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

Product Name:Brand Tykerb, generic lapatinib	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LAPATINIB DITOSYLATE	LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)	21533026100320	Generic

TYKERB	LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)	21533026100320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease

3 . References

Tykerb Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. March 2022.

Geyer CE, Forster J, Lindquist D, et al. Lapatinib plus capecitabine for HER2-positive advanced breast cancer. N Engl J Med. 2006;355(26):2733-2743.

National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium. National Comprehensive Cancer Network, Inc. 2020. Accessed August 26, 2022.

DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed August 12, 2020.

Moy B, Goss PE. Lapatinib: current status and future directions in breast cancer. Oncologist. 2006;11:1047-57.

Gomez H, Doval D, Chavez M, et al. Efficacy and safety of lapatinib as first-line therapy for ErbB2-amplified locally advanced or metastatic breast cancer. J Clin Oncol. 2008 May 5 [Epub ahead of print].

Lapatinib Prescribing Information. Lupin Pharmaceuticals, Inc. Baltimore, MD. November 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Tymlos (abaloparatide injection)

Prior Authorization Guideline

Guideline ID	GL-228727
Guideline Name	Tymlos (abaloparatide injection)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tymlos (abaloparatide injection)
Postmenopausal women with osteoporosis at high risk of fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Tymlos reduces the risk of vertebral fractures and nonvertebral fractures. **Increase Bone Density in Men with Osteoporosis at High Risk for Fracture** Indicated to increase bone density in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name:Tymlos	
Approval Length	24 month(s)*
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYMLOS	ABALOPARATIDE SUBCUTANEOUS SOLN PEN-INJECTOR 3120 MCG/1.56ML	3004400500D230	Brand

Approval Criteria

1 - One of the following diagnoses:

1.1 Postmenopausal osteoporosis or osteopenia

OR

1.2 Primary or hypogonadal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,5]

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [A]

Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions

Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime [1,2]	
Notes	Parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) not to exceed the FDA-recommended treatment duration of 2 years. *Tymlos will not be approved if the patient has already received 24 months of therapy; if the patient has not yet received 24 months of therapy, approval may be granted for the balance of the time remaining.

3 . Definitions

Definition	Description
Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean BMD of a young adult reference population (T-score between − 1.0 and − 2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration of bone tissue, decreased bone strength, bone fragility, and a consequent increase in fracture risk; BMD 2.5 or more standard deviations below the mean BMD of a young adult reference population (T-score at or below − 2.5).
T-score [3]	In describing BMD, the number of standard deviations above or below the mean BMD of a young adult reference population.

4 . Endnotes

The WHO FRAX tool is available at www.shef.ac.uk/FRAX and incorporates multiple clinical factors that predict fracture risk, largely independent of BMD. [2]

5 . References

Tymlos prescribing information. Radius Health, Inc. Waltham, MA. December 2023.

American Association of Clinical Endocrinologists medical guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis: 2020 update. Available at: https://pro.aace.com/disease-state-resources/bone-and-parathyroid/clinical-practice-guidelines/clinical-practice. Accessed May 6, 2021.

The Bone Health and Osteoporosis Foundation (BHOF). Clinician's guide to prevention and treatment of osteoporosis. Washington (DC): The Bone Health and Osteoporosis Foundation (BHOF); 2022

Per clinical consultation with endocrinologists. January 23 & 30, 2018.

Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An endocrine society clinical practice guideline. J Clin Endocrin Metab. 2019; 104(5):1595-1622.

Watts NB, Adler RA, Bilezikian JP, et al. Endocrine Society. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012;97(6):1802-22.

Prior Authorization Guideline

Guideline ID	GL-229166
Guideline Name	Tyrvaya (varenicline solution)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	12/15/2021
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Tyrvaya (varenicline solution) nasal spray
Dry Eye Disease Indicated for the treatment of the signs and symptoms of dry eye disease.

2 . Criteria

Product Name:Tyrvaya	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYRVAYA	VARENICLINE TARTRATE NASAL SOLN 0.03 MG/ACT	86280080202020	Brand

Approval Criteria

1 - Diagnosis of dry eye disease

AND

2 - Trial and failure, contraindication, or intolerance to at least one OTC ocular lubricant (e.g., artificial tears, lubricating gels/ointments) [B, 2-4]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following:

Restasis (cyclosporine 0.05%)

Xiidra (lifitegrast)

AND

4 - Prescribed by or in consultation with one of the following:

Ophthalmologist

Optometrist

Product Name:Tyrvaya	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYRVAYA	VARENICLINE TARTRATE NASAL SOLN 0.03 MG/ACT	86280080202020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy. (e.g., increased tear production or improvement in dry eye symptoms)

3 . Endnotes

Traditional diagnostic tests include the Schirmer test, ocular surface dye staining, tear function index/fluorescein clearance test, tear break up time, tear film osmolarity, slit lamp evaluation of lid [2-4]

As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (e.g., emulsions, gels, ointments). Anti-inflammatory therapies (e.g., topical cyclosporine, corticosteroids), systemic omega-3 fatty acid supplements, punctal plugs, and eyeglass side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management [2-4]

4 . References

Tyrvaya Prescribing Information. Oyster Point Pharma, Inc. Princeton, NJ. October 2021.

American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern. October 2018. Available at https://www.aaojournal.org/article/S0161-6420(18)32650-2/fulltext#tbl3. Accessed November 4, 2021.

Wood, S., Mian, S. Diagnostic Tools for Dry Eye Disease. Available at https://www.touchophthalmology.com/wp-content/uploads/sites/16/2017/01/Diagnostic-Tools-for-Dry-Eye-Disease_1.pdf. Accessed Nov 9. 2021.

Zeev, M., Miller, D, et al. Diagnosis of dry eye disease and emerging technologies. Clin Ophthalmol 2014;8:581-590. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3964175/#b16-opth-8-581. Accessed November 9, 2021.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-229023
Guideline Name	Tysabri (natalizumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tysabri (natalizumab)
Multiple Sclerosis (MS) Indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with Tysabri, physicians should consider whether the expected benefit of Tysabri is sufficient to offset this risk. **Crohn's Disease (CD)** Indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active CD with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha. In CD, Tysabri should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-alpha.

2 . Criteria

Product Name:Tysabri	
Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYSABRI	NATALIZUMAB FOR IV INJ CONC 300 MG/15ML	62405050001320	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [B]

AND

2 - One of the following:

2.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their multiple sclerosis [2]

OR

2.3 For continuation of prior therapy [2]

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Tysabri	
Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYSABRI	NATALIZUMAB FOR IV INJ CONC 300 MG/15ML	62405050001320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Tysabri

Diagnosis	Crohn’s Disease (CD)
Approval Length	3 Months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYSABRI	NATALIZUMAB FOR IV INJ CONC 300 MG/15ML	62405050001320	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Crohn's disease has evidence of inflammation (e.g., elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes) [1,3]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [3, 7]:

corticosteroids (e.g., prednisone)

6-mercaptopurine

azathioprine

methotrexate

AND

4 - Trial and failure, contraindication, or intolerance to a tumor necrosis factor (TNF)-inhibitor (e.g., certolizumab pegol, adalimumab)

AND

5 - Not used in combination with TNF inhibitors (e.g., certolizumab pegol, adalimumab) or immunosuppressants (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name:Tysabri	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYSABRI	NATALIZUMAB FOR IV INJ CONC 300 MG/15ML	62405050001320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 3, 7]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

AND

2 - Not used in combination with TNF inhibitors (e.g., certolizumab pegol, adalimumab) or immunosuppressants (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

3 . Endnotes

To minimize the risk of progressive multifocal leukoencephalopathy, natalizumab must be administered as a monotherapy without concomitant immunosuppressive therapy. Aminosalicylates may be continued during treatment with Tysabri. [1, 3]

Of the four disease courses of MS, relapse-remitting MS (RRMS) is characterized primarily by relapse, while secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. Most patients with RRMS eventually develop SPMS. As a person transitions from RRMS to SPMS, the disease begins to worsen more steadily, with or without occasional relapses, slight remissions, or plateaus. As long as the patient continues to have relapses, the SPMS course is considered to be both progressive and relapsing. [4]

In the postmarketing setting, additional cases of PML have been reported in multiple sclerosis and Crohn’s disease patients who were receiving no concomitant immunomodulatory therapy. Three factors that are known to increase the risk of PML in Tysabri-treated patients have been identified: 1) Longer treatment duration, especially beyond 2 years. 2) Prior treatment with an immunosuppressant (e.g., mitoxantrone, azathioprine, methotrexate, cyclophosphamide, mycophenolate mofetil). 3) The presence of anti-JCV antibodies. Patients who are anti-JCV antibody positive have a higher risk for developing PML. [1]

Tysabri should be discontinued in patients with Crohn’s disease who have not experienced therapeutic benefit by 12 weeks of induction therapy. For patients with Crohn’s disease who start Tysabri while on chronic oral corticosteroids, steroid tapering should begin as soon as a therapeutic benefit of Tysabri has occurred. Tysabri should be discontinued if patients cannot be tapered off of oral corticosteroids within six months of starting Tysabri. Other than the initial six-month taper, prescribers should consider discontinuing Tysabri for patients who require additional steroid use that exceeds three months in a calendar year to control their Crohn’s disease. [1]

4 . References

Tysabri Prescribing Information. Biogen Inc. Cambridge, MA. October 2023.

Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.

Lichtenstein GR, Loftus EV, Isaacs KL, et al. Management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.

National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed April 11, 2022.

FDA Drug Safety Communication: New risk factor for progressive multifocal leukoencephalopathy (PML) associated with Tysabri (natalizumab). January 20, 2012. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm288186.htm. Accessed April 11, 2022.

Nelson SML, Nguyen TM, McDonald J, MacDonald JK. Natalizumab for induction of remission in Crohn's disease. Cochrane Database of Systematic Reviews 2018, Issue 8. Art. No.: CD006097. DOI: 10.1002/14651858.CD006097.pub3.

Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Ultomiris (ravulizumab-cwvz)

Prior Authorization Guideline

Guideline ID	GL-229026
Guideline Name	Ultomiris (ravulizumab-cwvz)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ultomiris (ravulizumab-cwvz)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH). **Atypical Hemolytic Uremic Syndrome (aHUS)** Indicated for the treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA). Limitations of Use: Ultomiris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). **Generalized Myasthenia Gravis (gMG)** Indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive. **Neuromyelitis Optica Spectrum Disorder** Indicated for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name:Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

Product Name:Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS) [1]

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with one of the following:

Hematologist

Nephrologist

Product Name:Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., normalization of platelet count, improvement in serum creatinine from baseline) to therapy

Product Name:Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following: [2]

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

Chronic plasmapheresis or plasma exchange (PE)

Intravenous immunoglobulin (IVIG)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Ultomiris

Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Ultomiris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Ophthalmologist

Product Name:Ultomiris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

Ultomiris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. March 2024.

Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228568
Guideline Name	Unituxin (dinutuximab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Unituxin (dinutuximab)
Neuroblastoma Indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy.

2 . Criteria

Product Name:Unituxin	
Diagnosis	Neuroblastoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UNITUXIN	DINUTUXIMAB IV SOLN 17.5 MG/5ML (3.5 MG/ML)	21356028002020	Brand

Approval Criteria

1 - Diagnosis of high-risk neuroblastoma

AND

2 - Used in combination with all of the following:

Granulocyte-macrophage colony-stimulating factor (GM-CSF) [e.g., Leukine (sargramostim)]

Interleukin-2 (IL-2) [e.g., Proleukin (aldesleukin)]

13-cis-retinoic acid (RA) [e.g., isotretinoin]

AND

3 - Patient responded to prior first-line multiagent, multimodality therapy (e.g., chemotherapy, surgery, stem cell transplant, radiation therapy)

3 . References

Unituxin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. April 2024.

Prior Authorization Guideline

Guideline ID	GL-228569
Guideline Name	Uplizna (inebilizumab-cdon)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Uplizna (inebilizumab-cdon)
Neuromyelitis Optica Spectrum Disorder (NMOSD) Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name:Uplizna	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UPLIZNA	INEBILIZUMAB-CDON IV SOLN 100 MG/10ML (10 MG/ML)	99405040202020	Brand

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Ophthalmologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to rituximab

OR

4.2 For continuation of prior therapy

Product Name:Uplizna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UPLIZNA	INEBILIZUMAB-CDON IV SOLN 100 MG/10ML (10 MG/ML)	99405040202020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

Uplizna Prescribing Information. Horizon Therapeutics USA, Inc. Deerfield, IL. July 2021.

Prior Authorization Guideline

Guideline ID	GL-233217
Guideline Name	Upneeq (oxymetazoline hydrochloride)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/21/2020
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Upneeq (oxymetazoline hydrochloride ophthalmic solution)
Blepharoptosis Indicated for the treatment of acquired blepharoptosis in adults.

2 . Criteria

Product Name:Upneeq	
Diagnosis	Cosmetic Purposes
Guideline Type	Excluded Use

Product Name	Generic Name	GPI	Brand/Generic
UPNEEQ	OXYMETAZOLINE HCL OPHTH SOLN 0.1%	86802236102020	Brand

Approval Criteria

1 - Requests for coverage of Upneeq when used solely for lifting the eyelid to improve appearance is not authorized and will not be approved. This use is considered cosmetic only.

Product Name:Upneeq	
Diagnosis	Blepharoptosis
Approval Length	6 Week(s) [1, 4]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UPNEEQ	OXYMETAZOLINE HCL OPHTH SOLN 0.1%	86802236102020	Brand

Approval Criteria

1 - Both of the following:

Diagnosis of acquired blepharoptosis

Patient has obstructed visual field in primary gaze or down gaze due to blepharoptosis

AND

2 - One of the following: [2]

Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in primary gaze

Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in down gaze

Superior visual field loss of at least 12 degrees or 24 percent

AND

3 - Other treatable causes of blepharoptosis have been ruled out (e.g., recent botulinum toxin injection, myasthenia gravis)

AND

4 - Prescribed by or in consultation with an ophthalmologist or optometrist

Product Name:Upneeq	
Diagnosis	Blepharoptosis
Approval Length	6 Week(s) [1, 4]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UPNEEQ	OXYMETAZOLINE HCL OPHTH SOLN 0.1%	86802236102020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in superior visual field, increase in Marginal reflex distance-1 [MRD-1])

AND

2 - One of the following: [2]

Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in primary gaze

Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in down gaze

Superior visual field loss of at least 12 degrees or 24 percent

3 . References

Upneeq [package insert]. Bridgewater, NJ. RVL Pharmaceuticals, Inc. May 2023.

Cahill K, Bradley E, Meyer D et al. Functional Indications for Upper Eyelid Ptosis and Blepharoplasty Surgery. Ophthalmology. 2011;118(12):2510-2517.

Alsuhaibani A, Burkat C, Plemel D et al. Blepharoptosis - EyeWiki. Eyewiki.aao.org. https://eyewiki.aao.org/Blepharoptosis. Published 2020. Accessed September 2, 2021.

RVL Pharmaceuticals, Inc. Study of the Safety and Efficacy of RVL-1201 in the Treatment of Acquired Blepharoptosis. Available from: https://clinicaltrials.gov/ct2/show/NCT02436759. NCT02436759. Accessed September 2, 2021.

RVL Pharmaceuticals, Inc. Study of Safety and Efficacy of RVL-1201 in the Treatment of Blepharoptosis. Available from: https://clinicaltrials.gov/ct2/show/NCT03565887. NCT03565887. Accessed September 2, 2021.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228572
Guideline Name	Urea Cycle Disorder Agents - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Buphenyl (sodium phenylbutyrate)
Urea cycle disorders (UCDs) Indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). It is indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy. It is important that the diagnosis be made early and treatment initiated immediately to improve survival. Any episode of acute hyperammonemia should be treated as a life-threatening emergency.
Drug Name: Pheburane (sodium phenylbutyrate)
Urea cycle disorders (UCDs) Indicated as adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients with urea cycle disorders (UCDs), involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC) or argininosuccinic acid synthetase (AS). Limitations of use: Episodes of acute hyperammonemia may occur in patients while on Pheburane. Pheburane is not indicated for the treatment of acute hyperammonemia, which can be a life-

threatening medical emergency that requires rapid acting interventions to reduce plasma ammonia levels.

Drug Name: Ravicti (glycerol phenylbutyrate)

Urea cycle disorders (UCDs) Indicated for use as a nitrogen-binding agent for chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements). Limitations of use: Ravicti is not indicated for the treatment of acute hyperammonemia in patients with UCDs because more rapidly acting interventions are essential to reduce plasma ammonia levels. The safety and efficacy of Ravicti for the treatment of N-acetylglutamate synthase (NAGS) deficiency has not been established.

Drug Name: Olpruva (sodium phenylbutyrate)

Urea cycle disorders (UCDs) Indicated for use as a nitrogen-binding agent, as an adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). Limitations of Use: Olpruva is not indicated for the treatment of acute hyperammonemia

2 . Criteria

Product Name:Brand Buphenyl, generic sodium phenylbutyrate tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BUPHENYL	SODIUM PHENYLBUTYRATE TAB 500 MG	30908060000320	Brand
BUPHENYL	SODIUM PHENYLBUTYRATE ORAL POWDER 3 GM/TEASPOONFUL	30908060002950	Brand
SODIUM PHENYLBUTYRATE	SODIUM PHENYLBUTYRATE TAB 500 MG	30908060000320	Generic

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of urea cycle disorder (UCD)

AND

1.2 One of the following deficiencies:

carbamylphosphate synthetase (CPS)

ornithine transcarbamylase (OTC)

argininosuccinic acid synthetase (AS)

AND

2 - Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene [2]

AND

3 - Trial and failure, or intolerance to generic sodium phenylbutyrate powder

AND

4 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

5 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name:Pheburane	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PHEBURANE	SODIUM PHENYLBUTYRATE ORAL PELLETS 483 MG/GM	30908060008920	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of urea cycle disorder (UCD)

AND

1.2 One of the following deficiencies:

carbamylphosphate synthetase (CPS)

ornithine transcarbamylase (OTC)

argininosuccinic acid synthetase (AS)

AND

2 - Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene [2]

AND

3 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

4 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name:Olpruva, Ravicti	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RAVICTI	GLYCEROL PHENYLBUTYRATE LIQUID 1.1 GM/ML	30908030000920	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 2 GM THERAPY PACK	3090806000B120	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 3 GM THERAPY PACK	3090806000B130	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 4 GM THERAPY PACK	3090806000B140	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 5 GM THERAPY PACK	3090806000B150	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 6 GM THERAPY PACK	3090806000B160	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 6.67 GM THERAPY PACK	3090806000B170	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of urea cycle disorder (UCD)

AND

1.2 One of the following deficiencies:

carbamylphosphate synthetase (CPS)

ornithine transcarbamylase (OTC)

argininosuccinic acid synthetase (AS)

AND

2 - Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene [2]

AND

3 - Inadequate response to one of the following:

Dietary protein restriction

Amino acid supplementation

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Patient is 18 years of age or older

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

generic sodium phenylbutyrate powder

Pheburane

OR

4.2 Both of the following:

4.2.1 Patient is less than 18 years of age

AND

4.2.2 Trial and failure, contraindication or intolerance to one of the following:

Generic sodium phenylbutyrate powder

Pheburane

AND

5 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

6 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name:Brand Buphenyl, generic sodium phenylbutyrate tablet, Pheburane	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BUPHENYL	SODIUM PHENYLBUTYRATE TAB 500 MG	30908060000320	Brand
BUPHENYL	SODIUM PHENYLBUTYRATE ORAL POWDER 3 GM/TEASPOONFUL	30908060002950	Brand
SODIUM PHENYLBUTYRATE	SODIUM PHENYLBUTYRATE TAB 500 MG	30908060000320	Generic
PHEBURANE	SODIUM PHENYLBUTYRATE ORAL PELLETS 483 MG/GM	30908060008920	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., plasma ammonia and amino acid levels within normal limits)

AND

2 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

3 - Trial and failure, or intolerance to generic sodium phenylbutyrate powder [Applies to Brand Buphenyl and generic sodium phenylbutyrate tablet only]

Product Name:Olpruva, Ravicti	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RAVICTI	GLYCEROL PHENYLBUTYRATE LIQUID 1.1 GM/ML	30908030000920	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 2 GM THERAPY PACK	3090806000B120	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 3 GM THERAPY PACK	3090806000B130	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 4 GM THERAPY PACK	3090806000B140	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 5 GM THERAPY PACK	3090806000B150	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 6 GM THERAPY PACK	3090806000B160	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 6.67 GM THERAPY PACK	3090806000B170	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., plasma ammonia and amino acid levels within normal limits)

AND

2 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 18 years of age or older

AND

3.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

generic sodium phenylbutyrate powder

Pheburane

OR

3.2 Both of the following:

3.2.1 Patient is less than 18 years of age

AND

3.2.2 Trial and failure, contraindication or intolerance to one of the following:

generic sodium phenylbutyrate powder

Pheburane

Product Name:Buphenyl	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
BUPHENYL	SODIUM PHENYLBUTYRATE TAB 500 MG	30908060000320	Brand
BUPHENYL	SODIUM PHENYLBUTYRATE ORAL POWDER 3 GM/TEASPOONFUL	30908060002950	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of urea cycle disorder (UCD)

AND

1.2 One of the following deficiencies:

carbamylphosphate synthetase (CPS)

ornithine transcarbamylase (OTC)

argininosuccinic acid synthetase (AS)

AND

2 - Submission of medical records (e.g., chart notes) confirming molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene [2]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic sodium phenylbutyrate powder

AND

4 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

5 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name:Olpruva, Ravicti	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
RAVICTI	GLYCEROL PHENYLBUTYRATE LIQUID 1.1 GM/ML	30908030000920	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 2 GM THERAPY PACK	3090806000B120	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 3 GM THERAPY PACK	3090806000B130	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 4 GM THERAPY PACK	3090806000B140	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 5 GM THERAPY PACK	3090806000B150	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 6 GM THERAPY PACK	3090806000B160	Brand
OLPRUVA	SODIUM PHENYLBUTYRATE PACKET FOR SUSP 6.67 GM THERAPY PACK	3090806000B170	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of urea cycle disorder (UCD)

AND

1.2 One of the following deficiencies:

carbamylphosphate synthetase (CPS)

ornithine transcarbamylase (OTC)

argininosuccinic acid synthetase (AS)

AND

2 - Submission of medical records (e.g., chart notes) confirming molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene [2]

AND

3 - Inadequate response to one of the following:

Dietary protein restriction

Amino acid supplementation

AND

4 - One of the following:

4.1 All of the following:

4.1.1 ONE of the following:

Patient is new to Ravicti or Olpruva therapy

Patient has not previously been approved for Ravicti or Olpruva prior authorization with OptumRx

AND

4.1.2 ONE of the following:

4.1.2.1 Both of the following:

4.1.2.1.1 Patient is 18 years of age or older

AND

4.1.2.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

generic sodium phenylbutyrate powder

Pheburane

OR

4.1.2.2 Both of the following:

4.1.2.2.1 Patient is less than 18 years of age

AND

4.1.2.2.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to one of the following:

Generic sodium phenylbutyrate powder

Pheburane

OR

4.2 All of the following:

Previously been approved for a prior authorization for Ravicti or or Olpruva

Patient demonstrates positive clinical response to therapy (e.g., plasma ammonia and amino acid levels within normal limits)

Used as adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

5 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

3 . References

Buphenyl Prescribing Information. Ucyclyd Pharma, Inc. Scottsdale, AZ. April 2023.

Ah Mew N, Simpson KL, Gropman AL, et al. Urea Cycle Disorders Overview. 2003 [updated 2017]. In: Adam MP, Ardinger HH, Pagon RA, Wallace SE, Bean LJH, Gripp KW, Mirzaa GM, Amemiya A, eds. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993–2022. Urea Cycle Disorders Overview - GeneReviews® - NCBI Bookshelf (nih.gov). Accessed April 11, 2022.

Häberle J, Burlina A, Chakrapani A, et al. Suggested guidelines for the diagnosis and management of urea cycle disorders: First revision. J Inherit Metab Dis. 2019;42(6):1192-1230. doi: 10.1002/jimd.12100.

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Pheburane Prescribing Information. Medunik USA, Inc. Bryn Mawr, PA. August 2023.

Olpruva Prescribing Information. Acer Therapeutics Inc.. Newton, MA. December 2022.

UpToDate. Urea Cycle Disorders Management. Available at:https://www.uptodate.com/contents/urea-cycle-disorders-management?search=urea%20cycle%20disorders&source=search_result&selectedTitle=2~42&usage_type=default&display_rank=2. Accessed July 11, 2023.

Olpruva manufacturer Website. Available at: https://olpruva.com/?utm_source=google&utm_medium=cpc&utm_campaign=OLPRUVA+Patient+Launch&utm_content=Now+Available&utm_keyword=olpruva&utm_id=engage&gclid=EAIaIQobChMI5K700NKCgAMVUQx9Ch3R2AXrEAAYAiAAEgITp_D_BwE. Accessed July 11, 2023.

Prior Authorization Guideline

Guideline ID	GL-228729
Guideline Name	Vafseo (vadadustat) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vafseo (vadadustat)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months. Limitations of Use:Not been shown to improve quality of life, fatigue, or patient well-being. Not indicated for use as a substitute for transfusion in patients requiring immediate correction of anemia or in patients with anemia due to CKD not on dialysis.

2 . Criteria

Product Name:Vafseo	
Approval Length	6 Months [A, 1]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VAFSEO	VADADUSTAT TAB 150 MG	82402580000320	Brand
VAFSEO	VADADUSTAT TAB 300 MG	82402580000330	Brand

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Patient has been on dialysis for at least 3 months

AND

3 - Adequate iron stores confirmed by both of the following: [D, 1]

Patient's ferritin level is greater than 100mcg/L

Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Hemoglobin level less than 11 g/dL

AND

5 - Trial and failure, contraindication or intolerance to one of the following: [B, 1]

Retacrit

Procrit

Aranesp

AND

6 - Prescribed by or in consultation with one of the following:

hematologist

nephrologist

AND

7 - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

Product Name:Vafseo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VAFSEO	VADADUSTAT TAB 150 MG	82402580000320	Brand
VAFSEO	VADADUSTAT TAB 300 MG	82402580000330	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increase in hemoglobin)

AND

2 - Hemoglobin level does not exceed 11g/dL [C, 1]

AND

3 - Adequate iron stores confirmed by both of the following:

Patient's ferritin level is greater than 100mcg/L

Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Trial and failure, contraindication or intolerance to one of the following:

Retacrit

Procrit

Aranesp

AND

5 - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

Product Name:Vafseo	
Approval Length	6 Months [A, 1]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VAFSEO	VADADUSTAT TAB 150 MG	82402580000320	Brand
VAFSEO	VADADUSTAT TAB 300 MG	82402580000330	Brand

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has been on dialysis for at least 3 months

AND

3 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [D, 1]

Patient's ferritin level is greater than 100mcg/L

Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Submission of medical records (e.g., chart notes) confirming hemoglobin level less than 11 g/dL

AND

5 - One of the following:

5.1 Submission of medical records (e.g., chart notes) or paid claims confirming a minimum 12 -week trial and failure, to one of the following: [B, 1]

Retacrit

Procrit

Aranesp

OR

5.2 Submission of medical records (e.g., chart notes) confirming contraindication or intolerance to ALL of the following:

Retacrit

Procrit

Aranesp

AND

6 - Prescribed by or in consultation with one of the following:

hematologist

nephrologist

AND

7 - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

Product Name:Vafseo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VAFSEO	VADADUSTAT TAB 150 MG	82402580000320	Brand
VAFSEO	VADADUSTAT TAB 300 MG	82402580000330	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increase in hemoglobin)

AND

2 - Submission of medical records (e.g., chart notes) confirming hemoglobin level does not exceed 11g/dL [C, 1]

AND

3 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following:

Patient's ferritin level is greater than 100mcg/L

Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - One of the following:

4.1 Submission of medical records (e.g., chart notes) or paid claims confirming a minimum 12 -week trial and failure, to one of the following:

Retacrit

Procrit

Aranesp

OR

4.2 Submission of medical records (e.g., chart notes) confirming contraindication or intolerance to ALL of the following:

Retacrit

Procrit

Aranesp

AND

5 - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

3 . Endnotes

Efficacy in each study was based on the difference in mean change of Hb from baseline to the primary evaluation period (Weeks 24 to 36). [1]

In both the INNO2VATE-1 and INNO2VATE-2 trials, Vafseo was non-inferior to darbepoetin alfa in correcting and maintaining Hb levels. Recommended Starting Dose of Vafseo: Adults Not Being Treated with an ESA: The recommended starting dose is 300 mg orally once daily. Adults Being Switched from an ESA: When converting from an ESA to Vafseo, the recommended starting dose is 300 mg orally once daily. [1]

If the Hb level exceeds 11 g/dL, interrupt the dose of Vafseo until Hb is less than or equal to 11 g/dL then resume with a dose that is 150 mg less than the dose prior to interruption. [1]

Evaluate iron status in all patients before and during treatment. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%. The majority of patients with CKD will require supplemental iron during the course of therapy. [1]

4 . References

Vafseo Prescribing Information. Akebia Therapeutics, Inc. Cambridge, MA. March 2024.

ClinicalTrials.gov. Efficacy and Safety Study to Evaluate Vadadustat for the Correction or Maintenance Treatment of Anemia in Participants With Incident Dialysis-dependent Chronic Kidney Disease (DD-CKD) [NCT02865850]. Available at: https://www.clinicaltrials.gov/study/NCT02865850?cond=NCT02865850&rank=1#participation-criteria. Accessed August 5, 2024.

ClinicalTrials.gov. Efficacy and Safety Study to Evaluate Vadadustat for the Maintenance Treatment of Anemia in Participants With Dialysis-dependent Chronic Kidney Disease (DD-CKD). Available at : https://www.clinicaltrials.gov/study/NCT02892149?cond=NCT02892149&rank=1#participation-criteria. Accessed August 5, 2024.

Executive Summary of the KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease: Known Knowns AND Known Unknowns. Available at : https://kdigo.org/wp-content/uploads/2017/02/KDIGO-2024-CKD-Guideline-Executive-Summary.pdf. Accessed August 5, 2024.

Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Available at: https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-Anemia-Guideline-English.pdf. Accessed August 5, 2024.

Prior Authorization Guideline

Guideline ID	GL-228575
Guideline Name	Valchlor (mechlorethamine gel)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Valchlor (mechlorethamine gel)
Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) Indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy.

2 . Criteria

Product Name:Valchlor	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VALCHLOR	MECHLORETHAMINE HCL GEL 0.016% (BASE EQUIVALENT)	90371050204030	Brand

Approval Criteria

1 - One of the following diagnoses:

Stage IA mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL)

Stage IB mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL)

AND

2 - Patient has received at least one prior skin-directed therapy (e.g., topical corticosteroids [e.g., clobetasol, fluocinonide], phototherapy, bexarotene topical gel [Targretin topical gel], etc.)

Product Name:Valchlor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VALCHLOR	MECHLORETHAMINE HCL GEL 0.016% (BASE EQUIVALENT)	90371050204030	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Valchlor Prescribing Information. Helsinn Therapeutics (U.S.), Inc. Iselin, NJ. January 2020.

Prior Authorization Guideline

Guideline ID	GL-228577
Guideline Name	Vanflyta (quizartinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vanflyta (quizartinib)
Acute Myeloid Leukemia Indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test. Limitations of Use: Vanflyta is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with Vanflyta in this setting has not been demonstrated.

2 . Criteria

Product Name:Vanflyta

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VANFLYTA	QUIZARTINIB DIHYDROCHLORIDE TAB 17.7 MG	21533047100320	Brand
VANFLYTA	QUIZARTINIB DIHYDROCHLORIDE TAB 26.5 MG	21533047100325	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has a FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (FLT3-ITD) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Both of the following:

Used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) induction and cytarabine consolidation

Used as maintenance monotherapy following consolidation chemotherapy

Product Name:Vanflyta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

VANFLYTA	QUIZARTINIB DIHYDROCHLORIDE TAB 17.7 MG	21533047100320	Brand
VANFLYTA	QUIZARTINIB DIHYDROCHLORIDE TAB 26.5 MG	21533047100325	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Vanflyta Prescribing Information. Daiichi Sankyo, Inc., Basking Ridge. June 2024.

clinicaltrials.gov. Quizartinib With Standard of Care Chemotherapy and as Continuation Therapy in Patients With Newly Diagnosed FLT3-ITD (+) Acute Myeloid Leukemia (AML) (QuANTUM-First). Available at: https://clinicaltrials.gov/study/NCT02668653?term=nct02668653&rank=1. Accessed August 29, 2023.

Prior Authorization Guideline

Guideline ID	GL-228624
Guideline Name	Velsipity (etrasimod) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Velsipity (etrasimod)
Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

2 . Criteria

Product Name:Velsipity	
Diagnosis	Ulcerative Colitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VELSIPITY	ETRASIMOD ARGININE TAB 2 MG	52504525100350	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [2, 3]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, ESR, CRP)

Dependent on, or refractory to, corticosteroids

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following conventional therapies [2, 3]:

6-mercaptopurine

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

Azathioprine

Corticosteroids (e.g., prednisone)

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*:

One formulary adalimumab product

Simponi (golimumab)

Skyrizi (risankizumab-rzaa)

Stelara (ustekinumab)

Rinvoq (upadacitinib)

Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Zeposia (ozanimod)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Velsipity therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

AND

5 - Prescribed by or in consultation with a gastroenterologist

Notes	* Includes attestation that the patient has failed to respond to the TNF inhibitor mechanism of action in the past and should not be made to tr y a second TNF inhibitor. In this case, only a single step through a pre ferred agent is required. ** For review process only: Refer to the table in the Background sectio n for carrier-specific formulary adalimumab products

Product Name:Velsipity	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VELSIPITY	ETRASIMOD ARGININE TAB 2 MG	52504525100350	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

Product Name:Velsipity	
Diagnosis	Ulcerative Colitis
Approval Length	6 month(s)

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VELSIPITY	ETRASIMOD ARGININE TAB 2 MG	52504525100350	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [2, 3]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, ESR, CRP)

Dependent on, or refractory to, corticosteroids

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following conventional therapies [2, 3]:

6-mercaptopurine

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

Azathioprine

Corticosteroids (e.g., prednisone)

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*:

One formulary adalimumab product

Simponi (golimumab)

Skyrizi (risankizumab-rzaa)

Stelara (ustekinumab)

Rinvoq (upadacitinib)

Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Zeposia (ozanimod)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Velsipity therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline Reversal of high fecal output state **AND** **5** - Prescribed by or in consultation with a gastroenterologist	
Notes	* Includes attestation that the patient has failed to respond to the TNF inhibitor mechanism of action in the past and should not be made to tr y a second TNF inhibitor. In this case, only a single step through a pre ferred agent is required. ** For review process only: Refer to the table in the Background sectio n for carrier-specific formulary adalimumab products

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products **Adalimumab-adaz** **Hyrimoz** **Hadlima** **Adalimumab-fkjp**

4 . References

Velsipity Prescribing Information. Pfizer Labs. New York, NY. October 2023.

Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.

Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

5 . Revision History

Date	Notes
11/7/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-228579
Guideline Name	Vemlidy (tenofovir alafenamide) - ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vemlidy (tenofovir alafenamide tablet)
Chronic Hepatitis B (HBV) Indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults and pediatric patients 6 years of age and older with compensated liver disease.

2 . Criteria

Product Name:Vemlidy	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
VEMLIDY	TENOFOVIR ALAFENAMIDE FUMARATE TAB 25 MG	12352083200320	Brand

Approval Criteria

1 - All of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 One of the following:

1.2.1 Trial and failure, intolerance, or contraindication to generic entecavir

OR

1.2.2 Both of the following:

1.2.2.1 Patient is currently on Viread (tenofovir disoproxil fumarate)

AND

1.2.2.2 One of the following:

Patient has renal impairment

Patient has a diagnosis of osteoporosis

OR

2 - For continuation of prior therapy

Product Name:Vemlidy

Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VEMLIDY	TENOFOVIR ALAFENAMIDE FUMARATE TAB 25 MG	12352083200320	Brand

Approval Criteria

1 - All of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 One of the following:

1.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, intolerance, or contraindication to generic entecavir

OR

1.2.2 Paid claims or submission of medical records (e.g., chart notes) confirming both of the following:

1.2.2.1 Patient is currently on Viread (tenofovir disoproxil fumarate)

AND

1.2.2.2 One of the following:

Patient has renal impairment

Patient has a diagnosis of osteoporosis

OR

2 - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

Vemlidy Prescribing Information. Gilead Sciences, Inc. Foster City, CA. April 2024.

Prior Authorization Guideline

Guideline ID	GL-229028
Guideline Name	Venclexta (venetoclax)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Venclexta (venetoclax)
Chronic lymphocytic leukemia or Small lymphocytic lymphoma Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). **Acute Myeloid Leukemia** Indicated in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

2 . Criteria

Product Name:Venclexta

Diagnosis	Chronic lymphocytic leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VENCLEXTA STARTING PACK	VENETOCLAX TAB THERAPY STARTER PACK 10 & 50 & 100 MG	2147008000B720	Brand
VENCLEXTA	VENETOCLAX TAB 10 MG	21470080000320	Brand
VENCLEXTA	VENETOCLAX TAB 50 MG	21470080000340	Brand
VENCLEXTA	VENETOCLAX TAB 100 MG	21470080000360	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

Product Name:Venclexta	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VENCLEXTA STARTING PACK	VENETOCLAX TAB THERAPY STARTER PACK 10 & 50 & 100 MG	2147008000B720	Brand
VENCLEXTA	VENETOCLAX TAB 10 MG	21470080000320	Brand
VENCLEXTA	VENETOCLAX TAB 50 MG	21470080000340	Brand
VENCLEXTA	VENETOCLAX TAB 100 MG	21470080000360	Brand

Approval Criteria

1 - Diagnosis of AML

AND

2 - Disease is one of the following: [3]

Newly diagnosed

Relapsed

Refractory

Product Name:Venclexta	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VENCLEXTA STARTING PACK	VENETOCLAX TAB THERAPY STARTER PACK 10 & 50 & 100 MG	2147008000B720	Brand
VENCLEXTA	VENETOCLAX TAB 10 MG	21470080000320	Brand
VENCLEXTA	VENETOCLAX TAB 50 MG	21470080000340	Brand
VENCLEXTA	VENETOCLAX TAB 100 MG	21470080000360	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Venclexta Prescribing Information. AbbVie, Inc. North Chicago, IL. June 2022.

National comprehensive cancer network (NCCN) clinical practice guidelines in oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma. v.5.2019. Available from: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed June 4, 2019.

The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on September 7, 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229105
Guideline Name	Veopoz (pozelimab-bbfg)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/18/2023
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Veopoz (pozelimab-bbfg)
CD55-deficient protein-losing enteropathy (PLE) Indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

2 . Criteria

Product Name:Veopoz	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VEOPOZ	POZELIMAB-BBFG INJ SOLN 400 MG/2ML	85805070152020	Brand

Approval Criteria

1 - Diagnosis of active CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease

AND

2 - Patient has a confirmed genotype of biallelic CD55 loss-of-function mutation

AND

3 - Patient is 1 year of age or older

AND

4 - Patient has hypoalbuminemia (serum albumin concentration of less than or equal to 3.2 g/dL)

AND

5 - Patient has at least one of the following signs or symptoms within the last six months:

abdominal pain

diarrhea

peripheral edema

facial edema

AND

6 - Prescribed by or in consultation with one of the following:

Immunologist

Geneticist

Hematologist

Gastroenterologist

Product Name:Veopoz	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VEOPOZ	POZELIMAB-BBFG INJ SOLN 400 MG/2ML	85805070152020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g. decrease in albumin transfusions and hospitalizations, normalization of serum IgG concentrations, etc.)

3 . References

Veopoz Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. March 2024.

4 . Revision History

Date	Notes

1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228731
Guideline Name	Verkazia (cyclosporine ophthalmic emulsion 0.1%) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Verkazia (cyclosporine ophthalmic emulsion 0.1%)
Vernal Keratoconjunctivitis Indicated for the treatment of vernal keratoconjunctivitis in children and adults.

2 . Criteria

Product Name:Verkazia	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VERKAZIA	CYCLOSPORINE (OPHTH) EMULSION 0.1%	86720020001630	Brand

Approval Criteria

1 - Diagnosis of moderate to severe vernal keratoconjunctivitis confirmed by the presence of clinical signs and symptoms (e.g., itching, photophobia, giant papillae at the upper tarsal conjunctiva or at the limbus, thick mucus discharge, conjunctival hyperaemia) [A, 1, 2, 3]

AND

2 - Trial and failure, contraindication, or intolerance to ONE of the following:

Topical ophthalmic “dual-acting” mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine)

Topical ophthalmic mast cell stabilizers (e.g., cromolyn)

AND

3 - Trial and failure, contraindication, or intolerance, for short term use (up to 2 to 3 weeks), of topical ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluoromethalone)

AND

4 - Prescribed by or in consultation with ONE of the following: [B ,3]

Ophthalmologist

Optometrist

Product Name:Verkazia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VERKAZIA	CYCLOSPORINE (OPHTH) EMULSION 0.1%	86720020001630	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms (e.g., itching, photophobia, papillary hypertrophy, mucus discharge, conjunctival hyperaemia)

Product Name:Verkazia	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VERKAZIA	CYCLOSPORINE (OPHTH) EMULSION 0.1%	86720020001630	Brand

Approval Criteria

1 - Diagnosis of moderate to severe vernal keratoconjunctivitis confirmed by the presence of clinical signs and symptoms (e.g., itching, photophobia, giant papillae at the upper tarsal conjunctiva or at the limbus, thick mucus discharge, conjunctival hyperaemia) [A, 1, 2, 3]

AND

2 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure, contraindication, or intolerance to ONE of the following:

Topical ophthalmic “dual-acting” mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine)

Topical ophthalmic mast cell stabilizers (e.g., cromolyn)

AND

3 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure, contraindication, or intolerance, for short term use (up to 2 to 3 weeks), of topical ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluoromethalone)

AND

4 - Prescribed by or in consultation with ONE of the following: [B ,3]

Ophthalmologist

Optometrist

3 . Endnotes

No precise diagnostic criteria have been established for this disease. Diagnosis is based on typical clinical signs and symptoms; thus, many mild or atypical cases may escape diagnosis. The lack of standardized diagnostic criteria and lack of common language among physicians regarding the severity of VKC renders this disease more difficult to diagnose and treat. [2]

A short-term, high-dose pulse regimen of topical corticosteroids is often necessary in patients with VKC who fail to respond to two to three weeks of a dual-acting antihistamine/mast cell stabilizer, particularly those with significant seasonal exacerbations. Close follow-up with an ophthalmologist is required due to vision-threatening side effects of topical corticosteroids, such as glaucoma, cataracts, and secondary infections. Patients should know that blindness is a risk of unsupervised topical corticosteroid therapy. [3]

4 . References

Verkazia prescribing information. Santen, Inc. Emeryville, CA. June 2021.

Kumar, S. Vernal keratoconjunctivitis: a major review. Available at https://onlinelibrary.wiley.com/doi/10.1111/j.1755-3768.2008.01347.x. Accessed April 5, 2022.

UpToDate. Vernal keratoconjunctivitis. Available at https://www.uptodate.com/contents/vernal-keratoconjunctivitis?search=VERNAL%20KERATOCONJUNCTIVITIS&source=search_r

esult&selectedTitle=1~12&usage_type=default&display_rank=1#H18. Accessed April 5, 2022.

Prior Authorization Guideline

Guideline ID	GL-228581
Guideline Name	Verquvo (vericiguat)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Verquvo (vericiguat)
Chronic Heart Failure Indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

2 . Criteria

Product Name:Verquvo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VERQUVO	VERICIGUAT TAB 2.5 MG	40900085000321	Brand
VERQUVO	VERICIGUAT TAB 5 MG	40900085000330	Brand
VERQUVO	VERICIGUAT TAB 10 MG	40900085000340	Brand

Approval Criteria

1 - Diagnosis of chronic heart failure

AND

2 - Patient has an ejection fraction less than 45 percent

AND

3 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms

AND

4 - One of the following:

4.1 Patient was hospitalized for heart failure within the last 6 months

OR

4.2 Patient used outpatient intravenous diuretics (e.g., bumetanide, furosemide) for heart failure within the last 3 months

AND

5 - Trial and failure, contraindication, or intolerance to all of the following at a maximally tolerated dose: [1-4]

5.1 One of the following:

Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)

Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)]

AND

5.2 One of the following: [A, 4]

bisoprolol

carvedilol

metoprolol succinate extended-release

AND

5.3 Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformn)]

AND

5.4 Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name:Verquvo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VERQUVO	VERICIGUAT TAB 2.5 MG	40900085000321	Brand
VERQUVO	VERICIGUAT TAB 5 MG	40900085000330	Brand
VERQUVO	VERICIGUAT TAB 10 MG	40900085000340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

Per 2022 AHA/ACC/HFSA guideline for the management of Heart Failure, three beta blockers have been shown to be effective in reducing the risk of death in patients with HFrEF: bisoprolol, metoprolol succinate, and carvedilol. [4]

4 . References

Verquvo Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2023.

2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. Circulation. 2013 Oct 15;128(16):e240-327.

2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. J Card Fail. 2017 Aug;23(8):628-651.

Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. Journal of Cardiac Failure. Published online April 2022.

Verzenio (abemaciclib)

Prior Authorization Guideline

Guideline ID	GL-229029
Guideline Name	Verzenio (abemaciclib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Verzenio (abemaciclib)
Advanced or Metastatic Breast Cancer Indicated in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. **Advanced or Metastatic Breast Cancer** Indicated as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting. **Advanced or Metastatic Breast Cancer** Indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer. **Early Breast Cancer** Indicated in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence.

2 . Criteria

Product Name:Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VERZENIO	ABEMACICLIB TAB 50 MG	21531010000305	Brand
VERZENIO	ABEMACICLIB TAB 100 MG	21531010000310	Brand
VERZENIO	ABEMACICLIB TAB 150 MG	21531010000315	Brand
VERZENIO	ABEMACICLIB TAB 200 MG	21531010000320	Brand

Approval Criteria

1 - Diagnosis of breast cancer

Product Name:Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VERZENIO	ABEMACICLIB TAB 50 MG	21531010000305	Brand
VERZENIO	ABEMACICLIB TAB 100 MG	21531010000310	Brand
VERZENIO	ABEMACICLIB TAB 150 MG	21531010000315	Brand
VERZENIO	ABEMACICLIB TAB 200 MG	21531010000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Verzenio Prescribing Information. Lilly USA, LLC. Indianapolis, IN. March 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Viibryd (vilazodone)

Prior Authorization Guideline

Guideline ID	GL-228583
Guideline Name	Viibryd (vilazodone)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Viibryd	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
VIIBRYD	VILAZODONE HCL TAB 10 MG	58120088100310	Brand
VIIBRYD	VILAZODONE HCL TAB 20 MG	58120088100320	Brand
VIIBRYD	VILAZODONE HCL TAB 40 MG	58120088100340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), or intolerance to generic vilazodone

2 . References

Viibryd prescribing information. Allergan USA, Inc. Madison, NJ. September 2021.

Prior Authorization Guideline

Guideline ID	GL-228734
Guideline Name	Vijoice (alpelisib) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vijoice (alpelisib)
PIK3CA-Related Overgrowth Spectrum (PROS) Indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name:Vijoice	
Approval Length	6 months [A]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIJOICE	ALPELISIB (PROS) TAB THERAPY PACK 50 MG DAILY DOSE	9948601000B720	Brand
VIJOICE	ALPELISIB (PROS) TAB THERAPY PACK 125 MG DAILY DOSE	9948601000B730	Brand
VIJOICE	ALPELISIB (PROS) PAK 250 MG DAILY DOSE (200 MG & 50 MG TABS)	9948601000B740	Brand
VIJOICE	ALPELISIB (PROS) ORAL GRANULES PACKET 50 MG	99486010003020	Brand

Approval Criteria

1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

AND

2 - Documentation of mutation in the PIK3CA gene

AND

3 - Patient is 2 years of age or older

AND

4 - Documentation of severe clinical manifestations (e.g., Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal [CLOVES], Facial Infiltrating Lipomatosis [FIL], Klippel-Trenaunay Syndrome [KTS], Megalencephaly-Capillary Malformation Polymicrogyria [MCAP])

Product Name:Vijoice	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIJOICE	ALPELISIB (PROS) TAB THERAPY PACK 50 MG DAILY DOSE	9948601000B720	Brand
VIJOICE	ALPELISIB (PROS) TAB THERAPY PACK 125 MG DAILY DOSE	9948601000B730	Brand
VIJOICE	ALPELISIB (PROS) PAK 250 MG DAILY DOSE (200 MG & 50 MG TABS)	9948601000B740	Brand
VIJOICE	ALPELISIB (PROS) ORAL GRANULES PACKET 50 MG	99486010003020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., radiological response defined as a ≥ 20% reduction from baseline in the sum of target lesion volume)

Product Name:Vijoice	
Approval Length	6 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VIJOICE	ALPELISIB (PROS) TAB THERAPY PACK 50 MG DAILY DOSE	9948601000B720	Brand
VIJOICE	ALPELISIB (PROS) TAB THERAPY PACK 125 MG DAILY DOSE	9948601000B730	Brand
VIJOICE	ALPELISIB (PROS) PAK 250 MG DAILY DOSE (200 MG & 50 MG TABS)	9948601000B740	Brand
VIJOICE	ALPELISIB (PROS) ORAL GRANULES PACKET 50 MG	99486010003020	Brand

Approval Criteria

1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

AND

2 - Submission of medical records (e.g., chart notes) confirming documentation of mutation in the PIK3CA gene

AND

3 - Patient is 2 years of age or older

AND

4 - Submission of medical records (e.g., chart notes) confirming documentation of severe clinical manifestations (e.g., Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal [CLOVES], Facial Infiltrating Lipomatosis [FIL], Klippel-Trenaunay Syndrome [KTS], Megalencephaly-Capillary Malformation Polymicrogyria [MCAP])

Product Name:Vijoice	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VIJOICE	ALPELISIB (PROS) TAB THERAPY PACK 50 MG DAILY DOSE	9948601000B720	Brand
VIJOICE	ALPELISIB (PROS) TAB THERAPY PACK 125 MG DAILY DOSE	9948601000B730	Brand
VIJOICE	ALPELISIB (PROS) PAK 250 MG DAILY DOSE (200 MG & 50 MG TABS)	9948601000B740	Brand
VIJOICE	ALPELISIB (PROS) ORAL GRANULES PACKET 50 MG	99486010003020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., radiological response defined as a ≥ 20% reduction from baseline in the sum of target lesion volume)

3 . Endnotes

Patients without any response assessment at Week 24 were considered non-responders. [1]

4 . References

Vijoice Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. April 2024.

Prior Authorization Guideline

Guideline ID	GL-229169
Guideline Name	Viltepso (viltolarsen) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/21/2020
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Viltepso (viltolarsen)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Viltepso. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 . Criteria

Product Name:Viltepso

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VILTEPSO	VILTOLARSEN IV SOLN 250 MG/5ML (50 MG/ML)	74600080002020	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Duchenne muscular dystrophy (DMD)

AND

1.2 Confirmed mutation of the dystrophin gene amenable to exon 53 skipping

AND

2 - Patient is 4 years of age or older

AND

3 - Prescribed by or in consultation with a neurologist with expertise in the treatment of DMD

AND

4 - Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly

AND

5 - Patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair) [2, 3]

Product Name:Viltepso	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VILTEPSO	VILTOLARSEN IV SOLN 250 MG/5ML (50 MG/ML)	74600080002020	Brand

Approval Criteria

1 - Patient is tolerating therapy

AND

2 - Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly

AND

3 - Prescribed by or in consultation with a neurologist with expertise in the treatment of DMD

AND

4 - Patient is maintaining ambulatory status without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair)

Product Name:Viltepso	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VILTEPSO	VILTOLARSEN IV SOLN 250 MG/5ML (50 MG/ML)	74600080002020	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

1.1 Diagnosis of Duchenne muscular dystrophy (DMD)

AND

1.2 Confirmed mutation of the dystrophin gene amenable to exon 53 skipping

AND

2 - Patient is 4 years of age or older

AND

3 - Prescribed by or in consultation with a neurologist with expertise in the treatment of DMD

AND

4 - Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair) [2, 3]

3 . References

Viltepso Prescribing Information. NS Pharma, Inc. Paramus, NJ. January 2023.

ClinicalTrials.gov. Safety and Dose Finding Study of NS-065/NCNP-01 in Boys With Duchenne Muscular Dystrophy (DMD). NCT02740972. Website. Available at: https://clinicaltrials.gov/ct2/show/NCT02740972?term=NCT02740972&draw=2&rank=1. Accessed September 19, 2024.

Per Clinical Consultation with a Pediatrician, April 25, 2019 and January 22, 2020.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Vimizim (elosulfase alfa)

Prior Authorization Guideline

Guideline ID	GL-228735
Guideline Name	Vimizim (elosulfase alfa)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vimizim (elosulfase alfa)
Mucopolysaccharidosis type IVA Indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

2 . Criteria

Product Name:Vimizim	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIMIZIM	ELOSULFASE ALFA SOLN FOR IV INFUSION 5 MG/5ML (1 MG/ML)	30907030052020	Brand

Approval Criteria

1 - Diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) confirmed by both of the following: [1-3]

1.1 Documented clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.)

AND

1.2 Documented reduced fibroblast or leukocyte GALNS enzyme activity or molecular genetic testing for mutations in the GALNS gene.

Product Name:Vimizim	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIMIZIM	ELOSULFASE ALFA SOLN FOR IV INFUSION 5 MG/5ML (1 MG/ML)	30907030052020	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy

3 . References

Vimizim prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. December 2019.

UptoDate. Mucopolysaccharidoses: Clinical features and diagnosis. Available at https://www.uptodate.com/contents/mucopolysaccharidoses-clinical-features-and-diagnosis?search=Mucopolysaccharidoses:%20clinical%20features%20and%20diagnosis.%20&source=search_result&selectedTitle=1~66&usage_type=default&display_rank=1. Accessed July 6, 2022.

Mucopolysaccharidosis IV. Available at https://rarediseases.org/rare-diseases/morquio-syndrome/#:~:text=Excessive%20amounts%20of%20keratan%20sulfate,to%20identify%20GALNS%20gene%20mutations. Accessed July 6, 2022.

Prior Authorization Guideline

Guideline ID	GL-228738
Guideline Name	Vimovo (naproxen/esomeprazole magnesium)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vimovo (naproxen/esomeprazole magnesium)
Osteoarthritis Indicated in adult and adolescent patients 12 years of age and older weighing at least 38 kg, requiring naproxen for symptomatic relief of arthritis and esomeprazole magnesium to decrease the risk for developing naproxen-associated gastric ulcers. The naproxen component is indicated for the relief of signs and symptoms of osteoarthritis in adults. Limitations of use: do not substitute Vimovo with the single-ingredient products of naproxen and esomeprazole magnesium. Vimovo is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products. Controlled studies do not extend beyond 6 months. **Rheumatoid Arthritis** Indicated in adult and adolescent patients 12 years of age and older weighing at least 38 kg, requiring naproxen for symptomatic relief of arthritis and esomeprazole magnesium to decrease the risk for developing naproxen-associated gastric ulcers. The naproxen component is indicated for the relief of signs and symptoms of rheumatoid arthritis in adults. Limitations of use: do not substitute Vimovo with the single-ingredient products of naproxen and esomeprazole magnesium. Vimovo is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products. Controlled studies do not extend beyond 6 months.

Ankylosing Spondylitis Indicated in adult and adolescent patients 12 years of age and older weighing at least 38 kg, requiring naproxen for symptomatic relief of arthritis and esomeprazole magnesium to decrease the risk for developing naproxen-associated gastric ulcers. The naproxen component is indicated for the relief of signs and symptoms of ankylosing spondylitis in adults. Limitations of use: do not substitute Vimovo with the single-ingredient products of naproxen and esomeprazole magnesium. Vimovo is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products. Controlled studies do not extend beyond 6 months.

Juvenile idiopathic arthritis (JIA) Indicated in adult and adolescent patients 12 years of age and older weighing at least 38 kg, requiring naproxen for symptomatic relief of arthritis and esomeprazole magnesium to decrease the risk for developing naproxen-associated gastric ulcers. The naproxen component is indication for the relief of signs and symptoms juvenile idiopathic arthritis (JIA) in adolescent patients. Limitations of use: do not substitute Vimovo with the single-ingredient products of naproxen and esomeprazole magnesium. Vimovo is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products. Controlled studies do not extend beyond 6 months.

Naproxen-associated gastric ulcers risk reduction Indicated in adult and adolescent patients 12 years of age and older weighing at least 38 kg, requiring naproxen for symptomatic relief of arthritis and esomeprazole magnesium to decrease the risk for developing naproxen-associated gastric ulcers. The esomeprazole magnesium component of Vimovo is indicated to decrease the risk of developing naproxen-associated gastric ulcers. Limitations of use: do not substitute Vimovo with the single-ingredient products of naproxen and esomeprazole magnesium. Vimovo is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products. Controlled studies do not extend beyond 6 months.

2 . Criteria

Product Name:Brand Vimovo, Generic naproxen/esomeprazole magnesium	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIMOVO	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 375-20 MG	66109902440620	Brand
VIMOVO	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 500-20 MG	66109902440640	Brand

NAPROXEN-ESOMEPRAZOLE	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 375-20 MG	66109902440620	Generic
NAPROXEN-ESOMEPRAZOLE	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 500-20 MG	66109902440640	Generic

Approval Criteria

1 - One of the following diagnoses:

Osteoarthritis

Rheumatoid arthritis

Ankylosing spondylitis

Juvenile idiopathic arthritis

AND

2 - One of the following [2]:

History of peptic ulcer disease

History of gastrointestinal (GI) bleeding, obstruction, or perforation

Erosive esophagitis

Used in combination with aspirin

AND

3 - History of a minimum 30 day trial and failure, or intolerance to two of the following generics:

etodolac

fenoprofen

flurbiprofen

ibuprofen

indomethacin

naproxen

ketoprofen

ketorolac

meloxicam

nabumetone

oxaprozin

piroxicam

sulindac

tolmetin

diclofenac

AND

4 - History of a minimum 30 day trial and failure, or intolerance to two of the following generic proton pump inhibitors:

rabeprazole

esomeprazole

lansoprazole

omeprazole

pantoprazole

omeprazole/sodium bicarbonate

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with brand Vimovo or generic naproxen/esomeprazole magnesium instead of taking individual products in combination

3 . References

Vimovo [prescribing information]. Deerfield, IL: Horizon Medicines, LLC; March 2022.

Solomon C. Upper Gastrointestinal Bleeding Due to a Peptic Ulcer. N Engl J Med. 2016;374:2367-2376.

Prior Authorization Guideline

Guideline ID	GL-228582
Guideline Name	Vitrakvi (larotrectinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vitrakvi (larotrectinib)
Solid Tumors Indicated for the treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation and are metastatic or where surgical resection is likely to result in severe morbidity, and have no satisfactory alternative treatments or that have progressed following treatment.

2 . Criteria

Product Name:Vitrakvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VITRAKVI	LAROTRECTINIB SULFATE CAP 25 MG (BASE EQUIVALENT)	21533835200120	Brand
VITRAKVI	LAROTRECTINIB SULFATE CAP 100 MG (BASE EQUIVALENT)	21533835200150	Brand
VITRAKVI	LAROTRECTINIB SULFATE ORAL SOLN 20 MG/ML (BASE EQUIVALENT)	21533835202020	Brand

Approval Criteria

1 - Presence of solid tumors (e.g., salivary gland, soft tissue sarcoma, infantile fibrosarcoma, thyroid cancer, lung, melanoma, colon, etc.) with positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.) [1]

AND

2 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations] [1]

AND

3 - Disease is one of the following:

Metastatic

Unresectable (including cases where surgical resection is likely to result in severe morbidity)

AND

4 - One of the following:

Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy)

Disease has no satisfactory alternative treatments

Product Name:Vitrakvi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VITRAKVI	LAROTRECTINIB SULFATE CAP 25 MG (BASE EQUIVALENT)	21533835200120	Brand
VITRAKVI	LAROTRECTINIB SULFATE CAP 100 MG (BASE EQUIVALENT)	21533835200150	Brand
VITRAKVI	LAROTRECTINIB SULFATE ORAL SOLN 20 MG/ML (BASE EQUIVALENT)	21533835202020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Vitrakvi Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. November 2023.

Vizimpro (dacomitinib)

Prior Authorization Guideline

Guideline ID	GL-233218
Guideline Name	Vizimpro (dacomitinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	12/19/2018
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Vizimpro (dacomitinib)
Non Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

2 . Criteria

Product Name:Vizimpro	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIZIMPRO	DACOMITINIB TAB 15 MG	21360019000320	Brand
VIZIMPRO	DACOMITINIB TAB 30 MG	21360019000330	Brand
VIZIMPRO	DACOMITINIB TAB 45 MG	21360019000340	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC) [2]

AND

2 - Disease is metastatic [2]

AND

3 - Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA): [2]

Exon 19 deletion

Exon 21 L858R substitution

Product Name:Vizimpro	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VIZIMPRO	DACOMITINIB TAB 15 MG	21360019000320	Brand

VIZIMPRO	DACOMITINIB TAB 30 MG	21360019000330	Brand
VIZIMPRO	DACOMITINIB TAB 45 MG	21360019000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Vizimpro prescribing information. Pfizer Labs. New York, NY. December 2020.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-small cell lung cancer v.4.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed September 11, 2022.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Vonjo (pacritinib)

Prior Authorization Guideline

Guideline ID	GL-228739
Guideline Name	Vonjo (pacritinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vonjo (pacritinib)
Primary or Secondary Myelofibrosis Indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L.

2 . Criteria

Product Name:Vonjo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VONJO	PACRITINIB CITRATE CAP 100 MG	21537550100120	Brand

Approval Criteria

1 - Diagnosis of ONE of the following:[1]

Primary myelofibrosis

Post-polycythemia vera myelofibrosis

Post-essential thrombocythemia myelofibrosis

AND

2 - Disease is intermediate or high risk [1]

AND

3 - Pre-treatment platelet count below 50 x 10^9/L [1]

Product Name:Vonjo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VONJO	PACRITINIB CITRATE CAP 100 MG	21537550100120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., symptom improvement, spleen volume reduction)

3 . Endnotes

There is no "gold standard" for the diagnosis of PMF, although criteria have been proposed by the Italian Society of Hematology, the World Health Organization (WHO), and others [4]

Secondary myelofibrosis refers to myelofibrosis that develops after polycythemia vera (PV) or essential thrombocythemia (ET). Our approach to evaluation and management of secondary myelofibrosis follows the suggestions for PMF [4]

4 . References

Vonjo Prescribing Information. CTI BioPharma Corp. Seattle, WA. February 2022.

The NCCN Clinical Practice Guidelines in Oncology - Myeloproliferative Neoplasms. Available at https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf . version 1.2024. Accessed April 24, 2024.

UpToDate. Myelofibrosis (MF): Management of primary MF and secondary MF. Available at https://www.uptodate.com/contents/myelofibrosis-mf-management-of-primary-mf-and-secondary-mf?search=vonjo&source=search_result&selectedTitle=1%7E1&usage_type=default&display_rank=1. Accessed April 24, 2024.

Leukemia and Lymphoma Society. Myelofibrosis. Available at https://www.lls.org/myeloproliferative-neoplasms/myelofibrosis. Accessed April 2, 2022.

Prior Authorization Guideline

Guideline ID	GL-228742
Guideline Name	Vonoprazan Containing Agents
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Voquezna Dual Pak (vonoprazan, amoxicillin)
Helicobacter pylori (H. pylori) Indicated for the treatment of Helicobacter pylori (H. pylori) in adults.
Drug Name: Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin)
Helicobacter pylori (H. pylori) Indicated for the treatment of Helicobacter pylori (H. pylori) in adults.
Drug Name: Voquezna (vonoprazan)
Healing and Relief of Heartburn associated with Erosive Esophagitis Indicated for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. **Maintenance of Healing and Relief of Heartburn associated with Erosive Esophagitis** Indicated to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.

Helicobacter pylori (H. pylori) Indicated in combination with amoxicillin and clarithromycin or in combination with amoxicillin for the treatment of H. pylori infection in adults.

Relief of Heartburn Associated with Non-Erosive Gastroesophageal Reflux Disease (NERD) Indicated for the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.

2 . Criteria

Product Name:Voquezna Dual Pak, Voquezna Triple Pak	
Diagnosis	Helicobacter pylori (H. pylori) Infection
Approval Length	1 month [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOQUEZNA DUAL PAK	AMOXICILLIN CAP 500 MG & VONOPRAZAN TAB 20 MG THERAPY PACK	4999320220B120	Brand
VOQUEZNA TRIPLE PAK	AMOXICILLIN CAP & CLARITHROMYCIN TAB & VONOPRAZAN TAB PACK	4999320320B120	Brand

Approval Criteria

1 - Diagnosis of Helicobacter pylori infection

AND

2 - Trial and failure, contraindication, or intolerance to ONE of the following first line treatment regimens [B, C, 1, 3]

Clarithromycin based therapy (e.g., clarithromycin based triple therapy, clarithromycin based concomitant therapy) [D]

Bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI])

Product Name:Voquezna 20mg tablet	
Diagnosis	Helicobacter pylori (H. pylori) Infection
Approval Length	1 month [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOQUEZNA	VONOPRAZAN FUMARATE TAB 20 MG (BASE EQUIV)	49275087100340	Brand

Approval Criteria

1 - Diagnosis of Helicobacter pylori infection

AND

2 - One of the following:

Used in combination with amoxicillin and clarithromycin for the treatment of H. pylori infection

Used in combination with amoxicillin for the treatment of H. pylori infection

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following first line treatment regimens [B, C, 1, 3]

Clarithromycin based therapy (e.g., clarithromycin based triple therapy, clarithromycin based concomitant therapy) [D]

Bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI])

Product Name:Voquezna 20mg tablet	
Diagnosis	Healing and Relief of Heartburn associated with Erosive Esophagitis
Approval Length	8 Week(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOQUEZNA	VONOPRAZAN FUMARATE TAB 20 MG (BASE EQUIV)	49275087100340	Brand

Approval Criteria

1 - Diagnosis of erosive esophagitis

AND

2 - Used for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis [E, 2, 6]

AND

3 - Trial (of a minimum 8-week supply) and inadequate response (within the last 365 days), contraindication, or intolerance to TWO of the following generic proton pump inhibitors (PPI's) [F, 9]

omeprazole

esomeprazole

pantoprazole

lansoprazole

rabeprazole

dexlansoprazole

Product Name:Voquezna 10mg tablet	
Diagnosis	Maintenance of Healing and Relief of Heartburn associated with Erosive Esophagitis
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOQUEZNA	VONOPRAZAN FUMARATE TAB 10 MG (BASE EQUIV)	49275087100320	Brand

Approval Criteria

1 - Used to maintain healing and relief of heartburn associated with erosive esophagitis

AND

2 - Trial (of a minimum 8-week supply) and inadequate response (within the last 365 days), contraindication, or intolerance to TWO of the following generic proton pump inhibitors (PPI's) [F, 9]

omeprazole

esomeprazole

pantoprazole

lansoprazole

rabeprazole

dexlansoprazole

Product Name:Voquezna 10mg tablet	
Diagnosis	Relief of Heartburn associated with Non-Erosive Gastroesophageal Reflux Disease
Approval Length	1 Month [G, 2]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOQUEZNA	VONOPRAZAN FUMARATE TAB 10 MG	49275087100320	Brand

Approval Criteria

1 - Diagnosis of non-erosive Gastroesophageal Reflux Disease

AND

2 - Both of the following: [M, 2, 14]

Patient has history of heartburn for at least 6 months

Heartburn symptoms are present for at least 4 days during any consecutive 7-day period

AND

3 - Trial (of a minimum 8-week supply) and inadequate response (within the last 365 days), contraindication, or intolerance to TWO of the following generic proton pump inhibitors (PPI's) [H-L,15-18]

omeprazole

esomeprazole

pantoprazole

lansoprazole

rabeprazole

dexlansoprazole

3 . Endnotes

H. pylori is an infectious disease that is typically treated with combinations of 2–3 antibiotics along with a PPI, taken concomitantly or sequentially. Current guidelines recommend extended (10 to 14 days) treatment with all antibiotic regimens for H. pylori. [1]

The American College of Gastroenterology, (ACG) treatment guideline for first-line and salvage therapies was last updated in 2017. The 2017 ACG guideline outlines evidence-based, frontline treatment strategies for providers in North America. These include clarithromycin triple therapy, bismuth quadruple therapy, concomitant therapy, sequential therapy, hybrid therapy, levofloxacin triple therapy. Due to the complexity of treatment,

hybrid therapy as first line treatment is limited. Sequential therapy is also complex, and it is not uniformly endorsed as first line treatment. Due to the rising rates of levofloxacin resistance, levofloxacin should not be used for treatment, unless the H. pylori strain is known to be sensitive to it or if levofloxacin resistance rates are known to be less than 15 %. Studies evaluating the efficacy of levofloxacin containing regimens in North America are lacking. In clinical practice, the initial course of eradication therapy, heretofore referred to as “first-line” therapy, generally offers the greatest likelihood of treatment success. Thus, careful attention to the selection of the most appropriate first-line eradication therapy for an individual patient is essential. The ACG guidelines for the treatment of H pylori recommend several regimens for 1st line eradication therapy with no preference of 1 regimen over another. Therapy is individualized based on patient's previous antibiotic history and local resistance patterns. [1, 4]

In the selection of the most appropriate empiric treatment regimen for H pylori, previous antibiotic exposure, regional antibiotic-resistance patterns, and eradication rates should be taken into consideration because these factors can impact successful treatment. Successful treatment also relies on host factors such as allergies and adherence. [3]

Clarithromycin triple therapy consists of a PPI, clarithromycin, and amoxicillin or metronidazole. Clarithromycin based concomitant therapy consists of a PPI, amoxicillin, clarithromycin, and a nitroimidazole (e.g., tinidazole or metronidazole) [1, 4]

Esophagitis will be graded according to the LA Classification of Esophagitis, Grades A to D [2,6]

PPI's are recommended for the healing and maintenance of healing from erosive esophagitis. Meta-analyses suggest that overall GERD symptom relief and healing rates differ little among the available PPIs. There is conceptual rationale for a trial of switching PPIs for patients who have not responded to one PPI. For patients who have not responded to one PPI, more than one switch to another PPI cannot be supported. [9]

The effectiveness and safety of Voquezna was evaluated in a randomized, placebo-controlled, double-blind, four-week efficacy trial with a 20-week safety extension. [2]

Acid-suppressive therapy with proton-pump inhibitors (PPIs) is a mainstay in the treatment of non-erosive Gastroesophageal Reflux Disease. [15]

Proton pump inhibitors (PPIs) have been shown to be superior to histamine-2–receptor antagonists in patients with NERD. [16]

Treatment for NERD is similar to that for erosive GERD. [17]

For patients with classic GERD symptoms of heartburn and regurgitation who have no alarm symptoms, we recommend an 8-week trial of empiric proton pump inhibitor (PPI) once daily before a meal. We recommend attempting to discontinue the PPIs in patients whose classic GERD symptoms respond to an 8-week empiric trial of PPIs. For GERD patients who do not have erosive esophagitis or Barrett’s esophagus, and whose symptoms have resolved with PPI therapy, an attempt should be made to discontinue PPIs or to switch to on-demand therapy in which PPIs are taken only when symptoms occur and discontinued when they are relieved. [18]

PPIs are the most commonly prescribed medication based on ample data demonstrating consistently superior heartburn and regurgitation relief, as well as improved healing compared to H2RAs. Studies on GERD treatment typically last only 8-12 weeks, in part because symptom relief and healing appear to peak in that time frame. In some cases, patients with NERD and otherwise non-complicated GERD can be managed successfully with on-demand or intermittent PPI therapy. Switching PPIs can be considered for patients who experience minor side PPI effects including headache, abdominal pain, nausea, vomiting, diarrhea, constipation and flatulence. [18]

Per clinical trials, patient had to have history of heartburn for at least 6 months and heartburn was present on at least 4 or more days during any consecutive 7-day period. [14]

4 . References

Chey WD, Leontiadis GI, Howden CW, et al. ACG Clinical Guideline: Treatment of Helicobacter pylori infection. Am J Gastroenterol. 2017; 112:212-238

Voquezna prescribing information. Phathom Pharmaceuticals, Inc. Buffalo Grove, IL. July 2024.

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ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8754510/. Accessed August 5, 2024.

Voranigo (Vorasidenib)

Prior Authorization Guideline

Guideline ID	GL-229110
Guideline Name	Voranigo (Vorasidenib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/16/2024
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Voranigo (Vorasidenib)
Astrocytoma or Oligodendroglioma Indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection.

2 . Criteria

Product Name:Voranigo	
Diagnosis	Grade 2 Astrocytoma or Oligodendroglioma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VORANIGO	VORASIDENIB TAB 10 MG	21535180000320	Brand
VORANIGO	VORASIDENIB TAB 40 MG	21535180000340	Brand

Approval Criteria

1 - One of the following diagnoses:

1.1 Astrocytoma

OR

1.2 Oligodendroglioma

AND

2 - Presence of a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - History of one of the following:

Biopsy

Sub-total resection

Gross total resection

AND

4 - Patient is 12 years of age or older

Product Name:Voranigo	
Diagnosis	Grade 2 Astrocytoma or Oligodendroglioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VORANIGO	VORASIDENIB TAB 10 MG	21535180000320	Brand
VORANIGO	VORASIDENIB TAB 40 MG	21535180000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Voranigo Prescribing Information. Servier Pharmaceuticals LLC, , Boston, MA 02210. August 2024.

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4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-228584
Guideline Name	Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
Chronic Hepatitis C (CHC) Indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have: • Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor. • Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. (Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.)

2 . Criteria

Product Name:Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; without Decompensated Cirrhosis; Prior Relapser to NS5A-Based Regimen
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOSEVI	SOFOSBUVIR-VELPATASVIR-VOXILAPREVIR TAB 400-100-100 MG	1235990380033	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is a previous relapser to an NS5A-based regimen (e.g., Daklinza [daclatasvir]; Epclusa [sofosbuvir/velpatasvir]; Harvoni [ledipasvir/sofosbuvir]; Mavyret [glecaprevir/pibrentasvir]; Technivie [ombitasvir/paritaprevir/ritonavir]; Viekira [ombitasvir/paritaprevir/ritonavir & dasabuvir]; Zepatier [elbasvir/grazoprevir])

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	
Diagnosis	Chronic Hepatitis C - Genotype 1a or 3; without Decompensated Cirrhosis; Prior Relapser to Sofosbuvir-Based Regimen without an NS5A Inhibitor
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOSEVI	SOFOSBUVIR-VELPATASVIR-VOXILAPREVIR TAB 400-100-100 MG	12359903800330	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1a or 3

AND

2 - Patient is a previous relapser to a sofosbuvir-based regimen without an NS5A inhibitor

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name:Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; without Decompensated Cirrhosis; Prior Failure to Vosevi
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOSEVI	SOFOSBUVIR-VELPATASVIR-VOXILAPREVIR TAB 400-100-100 MG	12359903800330	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient had a prior treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [2]

AND

3 - Used in combination with ribavirin [2]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

3 . References

Vosevi Prescribing Information. Gilead Sciences, Inc. Foster City, CA. November 2019.

American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

Prior Authorization Guideline

Guideline ID	GL-229031
Guideline Name	Votrient (pazopanib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Votrient (pazopanib)
Renal Cell Carcinoma (RCC) Indicated for the treatment of patients with advanced renal cell carcinoma (RCC). **Soft tissue sarcoma (STS)** Indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. Limitation of Use: The efficacy of Votrient for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors has not been demonstrated.

2 . Criteria

Product Name:Brand Votrient, Generic pazopanib	
Diagnosis	Renal Cell Carcinoma (RCC)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOTRIENT	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Brand
PAZOPANIB HYDROCHLORIDE	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Generic

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following: [2]

Disease has relapsed

Diagnosis of stage IV disease

AND

3 - Trial and failure, or intolerance to generic pazopanib (applies to brand Votrient only)

AND

4 - One of the following: [2]

4.1 One of the following:

4.1.1 Both of the following:

Used in the treatment of non-clear cell renal cell carcinoma

Trial and failure, contraindication or intolerance to generic sunitinib

OR

4.1.2 For continuation of prior therapy

OR

4.2 Patient has clear cell renal cell carcinoma

Product Name:Brand Votrient, Generic pazopanib	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOTRIENT	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Brand
PAZOPANIB HYDROCHLORIDE	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure, or intolerance to generic pazopanib (applies to brand Votrient only)

AND

3 - One of the following:

3.1 One of the following:

3.1.1 Both of the following:

Used in the treatment of non-clear cell renal cell carcinoma

Trial and failure, contraindication or intolerance to generic sunitinib

OR

3.1.2 For continuation of prior therapy

OR

3.2 Patient has clear cell renal cell carcinoma

Product Name:Brand Votrient, Generic pazopanib	
Diagnosis	Soft tissue sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOTRIENT	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Brand
PAZOPANIB HYDROCHLORIDE	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Generic

Approval Criteria

1 - Diagnosis of advanced soft tissue sarcoma (STS) [4, A]

AND

2 - Trial and failure, or intolerance to generic pazopanib (Applies to Brand Votrient only)

Product Name:Brand Votrient, Generic pazopanib	
Diagnosis	Soft tissue sarcoma (STS)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOTRIENT	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Brand
PAZOPANIB HYDROCHLORIDE	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure, or intolerance to generic pazopanib (Applies to Brand Votrient only)

3 . Endnotes

Votrient is an active drug in anthracycline pretreated STS patients with an increase in median PFS of 13 weeks. [3]

4 . References

Votrient Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. December 2021.

National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Kidney cancer v.4.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed February 28, 2023.

PALETTE: a randomized, double-blind, phase III trial of pazopanib versus placebo in patients (pts) with soft-tissue sarcoma (STS) whose disease has progressed during or following prior chemotherapy-An EORTC STBSG Global Network Study (EORTC 62072). Available at: www.asco.org/ascov2/Meetings/Abstracts?&vmview=abst_detail_view&confID=102&abstractID=83283. Accessed April 30, 2012.

National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Soft tissue sarcoma v.2.2022. Available at: http://www.nccn.org/professionals/physician_gls/PDF/sarcoma.pdf. Accessed February 28, 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228586
Guideline Name	Voxzogo (vosoritide)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Voxzogo (vosoritide)
Increase linear growth in pediatric patients with achondroplasia Indicated to increase linear growth in pediatric patients with achondroplasia with open epiphyses. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name:Voxzogo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOXZOGO	VOSORITIDE FOR SUBCUTANEOUS INJ 0.4 MG	30950080002120	Brand
VOXZOGO	VOSORITIDE FOR SUBCUTANEOUS INJ 0.56 MG	30950080002130	Brand
VOXZOGO	VOSORITIDE FOR SUBCUTANEOUS INJ 1.2 MG	30950080002140	Brand

Approval Criteria

1 - Patient has open epiphyses

AND

2 - Diagnosis of achondroplasia as confirmed by one of the following: [2, 3]

2.1 Both of the following:

2.1.1 Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis)

AND

2.1.2 Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest)

OR

2.2 Molecular genetic testing confirmed c.1138G>A or c.1138G>C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene

AND

3 - Patient did not have limb-lengthening surgery in the previous 18 months and does not plan on having limb-lengthening surgery while on Voxzogo therapy

AND

4 - Prescribed by or in consultation with one of the following:

Clinical geneticist

Endocrinologist

A physician who has specialized expertise in the management of achondroplasia

Product Name:Voxzogo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOXZOGO	VOSORITIDE FOR SUBCUTANEOUS INJ 0.4 MG	30950080002120	Brand
VOXZOGO	VOSORITIDE FOR SUBCUTANEOUS INJ 0.56 MG	30950080002130	Brand
VOXZOGO	VOSORITIDE FOR SUBCUTANEOUS INJ 1.2 MG	30950080002140	Brand

Approval Criteria

1 - Patient continues to have open epiphyses

AND

2 - Patient demonstrates positive clinical response to therapy as evidenced by one of the following:

Improvement in annualized growth velocity (AGV) compared to baseline

Improvement in height Z-score compared to baseline

AND

3 - Prescribed by or in consultation with one of the following:

Clinical geneticist

Endocrinologist

A physician who has specialized expertise in the management of achondroplasia

3 . References

Voxzogo Prescribing Information. BioMarin Pharmaceutical Inc., Novato, CA. October 2023.

Pauli RM. Achondroplasia: a comprehensive clinical review. Orphanet J Rare Dis 2019;14(1):1-49.

Bacino CA. Achondroplasia. UpToDate. Available by subscription at: http://www.uptodate.com/. Accessed January 5, 2024.

Voydeya (danicopan)

Prior Authorization Guideline

Guideline ID	GL-233333
Guideline Name	Voydeya (danicopan)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	2/18/2025
P&T Approval Date:	5/16/2024
P&T Revision Date:	6/19/2024

1 . Indications

Drug Name: Voydeya (danicopan)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH). Limitations of Use: Voydeya has not been shown to be effective as monotherapy and should only be prescribed as an add-on to ravulizumab or eculizumab.

2 . Criteria

Product Name:Voydeya

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOYDEYA	DANICOPAN TAB THERAPY PACK 50 MG & 100 MG	8580852000B720	Brand
VOYDEYA	DANICOPAN TAB 100 MG	85808520000320	Brand

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Will be used as add-on therapy to Ultomiris (ravulizumab) or Soliris (eculizumab)

AND

3 - Hemoglobin levels less than or equal to 9.5 g/dL

AND

4 - Absolute reticulocyte count greater than or equal to 120 × 10^9 /L

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Voydeya	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOYDEYA	DANICOPAN TAB THERAPY PACK 50 MG & 100 MG	8580852000B720	Brand
VOYDEYA	DANICOPAN TAB 100 MG	85808520000320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions)

AND

2 - Will be used as add-on therapy to Ultomiris (ravulizumab) or Soliris (eculizumab)

3 . References

Voydeya Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. March 2024.

4 . Revision History

Date	Notes
2/18/2025	Quartz commercial copied to mirrow OptumRx

Vtama (tapinarof)

Prior Authorization Guideline

Guideline ID	GL-228743
Guideline Name	Vtama (tapinarof)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vtama (tapinarof) cream
Plaque Psoriasis (PsO) Indicated for the topical treatment of plaque psoriasis in adults.

2 . Criteria

Product Name:Vtama	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

VTAMA	TAPINAROF CREAM 1%	90250075003720	Brand

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to ONE of the following generic topical therapies [2]:

Corticosteroids (e.g., betamethasone, clobetasol)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Combination topical therapy (e.g., vitamin D analog/corticosteroid)

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name:Vtama	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VTAMA	TAPINAROF CREAM 1%	90250075003720	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by one of the following [1-2]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

3 . References

Vtama Prescribing Information. Dermavant Sciences Inc. Long Beach, CA. May 2022.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Prior Authorization Guideline

Guideline ID	GL-233399
Guideline Name	Vuity (pilocarpine) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	1/19/2022
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Vuity (pilocarpine)
Presbyopia of the eye Indicated for the treatment of presbyopia in adults.

2 . Criteria

Product Name:Vuity	
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VUITY	PILOCARPINE HCL OPHTH SOLN 1.25%	86501030102017	Brand

Approval Criteria

1 - Diagnosis of presbyopia

AND

2 - Prescribed by or in consultation with ONE of the following:

Ophthalmologist

Optometrist

AND

3 - Provider confirms valid clinical rationale, which excludes lifestyle choice, as to why patient is unable to use corrective lenses (e.g., eyeglasses or contact lenses)

Product Name:Vuity	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VUITY	PILOCARPINE HCL OPHTH SOLN 1.25%	86501030102017	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in near vision in low light conditions without lost of distance vision)

AND

2 - Prescribed by or in consultation with ONE of the following:

Ophthalmologist

Optometrist

Product Name:Vuity	
Approval Length	1 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VUITY	PILOCARPINE HCL OPHTH SOLN 1.25%	86501030102017	Brand

Approval Criteria

1 - Diagnosis of presbyopia

AND

2 - Prescribed by or in consultation with ONE of the following:

Ophthalmologist

Optometrist

AND

3 - Submission of medical records (e.g., chart notes) confirming valid clinical rationale, which excludes lifestyle choice, as to why patient is unable to use corrective lenses (e.g., eyeglasses or contact lenses)

3 . References

Vuity Prescribing Information. Abbvie Inc. North Chicago, IL. March 2023.

4 . Revision History

Date	Notes
3/14/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-229033
Guideline Name	Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)
Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) Indicated for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

2 . Criteria

Product Name:Vyndaqel, Vyndamax	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYNDAQEL	TAFAMIDIS MEGLUMINE (CARDIAC) CAP 20 MG	40550080200120	Brand
VYNDAMAX	TAFAMIDIS CAP 61 MG	40550080000120	Brand

Approval Criteria

1 - Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM)

AND

2 - One of the following: [3, 4]

2.1 Patient has a transthyretin (TTR) mutation (e.g., V122I)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits

OR

2.3 All of the following:

Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis

Scintigraphy scan suggestive of cardiac TTR amyloidosis

Absence of light-chain amyloidosis

AND

3 - One of the following: [2]

History of heart failure, with at least one prior hospitalization for heart failure

Presence of clinical signs and symptoms of heart failure (e.g., dyspnea, edema)

AND

4 - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure [2]

AND

5 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Diflunisal)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name:Vyndaqel, Vyndamax	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYNDAQEL	TAFAMIDIS MEGLUMINE (CARDIAC) CAP 20 MG	40550080200120	Brand
VYNDAMAX	TAFAMIDIS CAP 61 MG	40550080000120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

3 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Diflunisal)

AND

4 - Prescribed by or in consultation with a cardiologist

3 . References

Vyndaqel and Vyndamax prescribing information. Pfizer, Inc. New York, NY. April 2023.

Mauer MS, Schwartz JH, Gundapeneni B, et al. Tafamadis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018; 379:1007-16.

Gillmore JD, Maurer MS, Falk RH, et al. Nonbiopsy diagnosis of cardiac transthyretin amyloidosis. Circulation. 2016; 133:2404-12.

Nativi-Nicolau J and Maurer MS. Amyloidosis cardiomyopathy: update in the diagnosis and treatment of the most common types. Curr Opin Cardiol. 2018; 33(5):571-579.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228745
Guideline Name	Vyvgart (efgartigimod alfa-fcab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vyvgart (efgartigimod alfa)
Generalized Myasthenia Gravis (gMG) Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
Drug Name: Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
Generalized Myasthenia Gravis (gMG) Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. **Chronic inflammatory demyelinating polyneuropathy (CIDP)** Indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP)

2 . Criteria

Product Name:Vyvgart, Vyvgart Hytrulo	
Diagnosis	Generalized myasthenia gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYVGART	EFGARTIGIMOD ALFA-FCAB IV SOLN 400 MG/20ML	99398225302020	Brand
VYVGART HYTRULO	EFGARTIGIMOD ALF-HYALURONIDASE-QVFC SOL 180-2000 MG-UNIT/ML	99399902152020	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

Chronic plasmapheresis or plasma exchange (PE)

Intravenous immunoglobulin (IVIG)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Vyvgart, Vyvgart Hytrulo	
Diagnosis	Generalized myasthenia gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYVGART	EFGARTIGIMOD ALFA-FCAB IV SOLN 400 MG/20ML	99398225302020	Brand
VYVGART HYTRULO	EFGARTIGIMOD ALF-HYALURONIDASE-QVFC SOL 180-2000 MG-UNIT/ML	99399902152020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Vyvgart Hytrulo	
Diagnosis	Chronic inflammatory demyelinating polyneuropathy (CIDP)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYVGART HYTRULO	EFGARTIGIMOD ALF-HYALURONIDASE-QVFC SOL 180-2000 MG-UNIT/ML	99399902152020	Brand

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [3]:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:

1.2.1 Progressive or relapsing motor impairment of more than one limb

OR

1.2.2 Progressive or relapsing sensory impairment of more than one limb

AND

1.3 Electrophysiologic findings when three of the following four criteria are present:

Partial conduction block of 1 or more motor nerve

Reduced conduction velocity of 2 or more motor nerves

Prolonged distal latency of 2 or more motor nerves

Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

AND

2 - Trial and failure, contraindication, or intolerance to one of the following standard of care treatments [3][4]:

Corticosteroids (minimum 3 month trial duration)

Immunoglobulin

Plasma exchange

AND

3 - Prescribed by or in consultation with one of the following:

Immunologist

Neurologist

Hematologist

Product Name:Vyvgart Hytrulo	
Diagnosis	Chronic inflammatory demyelinating polyneuropathy (CIDP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYVGART HYTRULO	EFGARTIGIMOD ALF-HYALURONIDASE-QVFC SOL 180-2000 MG-UNIT/ML	99399902152020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., Improvement in INCAT or aINCAT score)

AND

2 - Prescribed by or in consultation one of the following:

Immunologist

Neurologist

Hematologist

3 . References

Vyvgart Prescribing Information. Argenx US, Inc. Boston, MA. April 2022.

Vyvgart Hytrulo Prescribing Information. Argenx US, Inc. Boston, MA. June 2024.

Koller H, Kieseier BC, Jander S, et al. Chronic inflammatory demyelinating polyneuropathy. N Engl J Med. 2005;352(13):1343-56.

Van den Bergh PYK, van Doorn PA, Hadden RDM et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force-Second revision. Eur J Neurol. 2021 Nov;28(11):3556-3583. doi: 10.1111/ene.14959. Epub 2021 Jul 30.

Prior Authorization Guideline

Guideline ID	GL-228588
Guideline Name	Vyxeos (daunorubicin and cytarabine)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vyxeos (daunorubicin and cytarabine)
Newly-diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC) Indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in adults and pediatric patients 1 year and older.

2 . Criteria

Product Name:Vyxeos	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYXEOS	DAUNORUBICIN-CYTARABINE LIPOSOME FOR IV INJ 44-100 MG	21990002201930	Brand

Approval Criteria

1 - One of the following diagnoses: [1-3]

Newly-diagnosed therapy-related acute myeloid leukemia (t-AML)

Newly-diagnosed acute myeloid leukemia with myelodysplasia-related changes (AML-MRC)

Product Name:Vyxeos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYXEOS	DAUNORUBICIN-CYTARABINE LIPOSOME FOR IV INJ 44-100 MG	21990002201930	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Vyxeos Prescribing Information. Jazz Pharmaceuticals. Palo Alto, CA. April 2021.

National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available by subscription at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 28,2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.3.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed May 28, 2021.

Prior Authorization Guideline

Guideline ID	GL-233400
Guideline Name	Wainua (eplontersen)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	3/20/2024
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Wainua (eplontersen)
Hereditary transthyretin-mediated amyloidosis Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

2 . Criteria

Product Name:Wainua	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WAINUA	EPLONTERSEN SODIUM SUBCUTANEOUS SOLN AUTO-INJ 45 MG/0.8ML	6270102510D520	Brand

Approval Criteria

1 - Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy

AND

2 - Presence of a transthyretin (TTR) mutation (e.g., V30M) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [1]

AND

3 - One of the following [2, 3]:

Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2

Patient has a baseline neuropathy impairment score (NIS) greater than or equal to 10 and less than or equal to 130

Patient has a baseline Karnofsky Performance Status score greater than 50%

AND

4 - Presence of clinical signs and symptoms of the disease (e.g., neuropathy, quality of life) [2]

AND

5 - Patient has not had a liver transplant [2, 3]

AND

6 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Vyndaqel)

AND

7 - Prescribed by or in consultation with a neurologist

Product Name:Wainua	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WAINUA	EPLONTERSEN SODIUM SUBCUTANEOUS SOLN AUTO-INJ 45 MG/0.8ML	6270102510D520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improved quality of life, decreased serum TTR level)

AND

2 - One of the following [2, 3]:

Patient continues to have a familial amyloidotic polyneuropathy (FAP) stage of 1 or 2

Patient continues to have a neuropathy impairment score (NIS) greater than or equal to 10 and less than or equal to 130

Patient continues to have a Karnofsky Performance Status score greater than 50%

AND

3 - Patient has not had a liver transplant [2, 3]

AND

4 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Vyndaqel)

3 . References

Wainua Prescribing Information. AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850. December 2023

Coelho T, Ando Y, Benson MD et al. Design and Rationale of the Global Phase 3 NEURO-TTRansform Study of Antisense Oligonucleotide AKCEA-TTR-LRx (ION-682884-CS3) in Hereditary Transthyretin-Mediated Amyloid Polyneuropathy. Neurol Ther. 2021 Jun;10(1):375-389. doi: 10.1007/s40120-021-00235-6. Epub 2021 Feb 26

Study Details | NEURO-TTRansform: A Study to Evaluate the Efficacy and Safety of Eplontersen (Formerly Known as ION-682884, IONIS-TTR-LRx and AKCEA-TTR-LRx) in Participants With Hereditary Transthyretin-Mediated Amyloid Polyneuropathy | ClinicalTrials.gov https://clinicaltrials.gov/study/NCT04136184. Accessed February 9, 2024.

4 . Revision History

Date	Notes
3/14/2025	Quartz guideline copied to mirrow Optumrx

Prior Authorization Guideline

Guideline ID	GL-228748
Guideline Name	Wakix (pitolisant)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Wakix (pitolisant)
Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1) Indicated for the treatment of cataplexy in adult patients with narcolepsy. **Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)** Indicated for the treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older with narcolepsy.

2 . Criteria

Product Name:Wakix	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WAKIX	PITOLISANT HCL TAB 4.45 MG (BASE EQUIVALENT)	61450070100318	Brand
WAKIX	PITOLISANT HCL TAB 17.8 MG (BASE EQUIVALENT)	61450070100338	Brand

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

2 - Symptoms of cataplexy are present

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Wakix	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WAKIX	PITOLISANT HCL TAB 4.45 MG (BASE EQUIVALENT)	61450070100318	Brand
WAKIX	PITOLISANT HCL TAB 17.8 MG (BASE EQUIVALENT)	61450070100338	Brand

Approval Criteria

1 - Patient demonstrates a reduction in the frequency of cataplexy attacks associated with therapy

OR

2 - Patient demonstrates a reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name:Wakix	
Diagnosis	Narcolepsy without cataplexy (Narcolepsy Type 2)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WAKIX	PITOLISANT HCL TAB 4.45 MG (BASE EQUIVALENT)	61450070100318	Brand
WAKIX	PITOLISANT HCL TAB 17.8 MG (BASE EQUIVALENT)	61450070100338	Brand

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [A, B]

AND

2 - Symptoms of cataplexy are absent

AND

3 - Patient is 6 years of age or older

AND

4 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

5 - BOTH of the following:

5.1 Trial and failure, contraindication (e.g., age), or intolerance to BOTH of the following:

Generic modafinil or armodafinil

Sunosi

AND

5.2 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant UNLESS patient is not a candidate

AND

6 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name:Wakix	
Diagnosis	Narcolepsy without cataplexy (Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WAKIX	PITOLISANT HCL TAB 4.45 MG (BASE EQUIVALENT)	61450070100318	Brand
WAKIX	PITOLISANT HCL TAB 17.8 MG (BASE EQUIVALENT)	61450070100338	Brand

Approval Criteria

1 - Patient demonstrates a reduction in symptoms of excessive daytime sleepiness associated with therapy

AND

2 - BOTH of the following:

2.1 Trial and failure, contraindication (e.g., age), or intolerance to BOTH of the following:

Generic modafinil or armodafinil

Sunosi

AND

2.2 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant UNLESS patient is not a candidate

3 . Endnotes

International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 1 (narcolepsy with cataplexy) require: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) The presence of one or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT; or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than or equal to 110 pg/mL or less than one-third of mean values obtained in normal subjects with the same standardized assay) [2,3].

International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 2 (narcolepsy without cataplexy) include: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) Cataplexy is absent. 3) CSF hypocretin-1 levels, if measured, is either greater than 100 pg/mL or greater than one-third of mean values obtained in normal subjects with the same standardized assay. 4) A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT. 5) Hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal [2,3].

4 . References

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Prior Authorization Guideline

Guideline ID	GL-233221
Guideline Name	Welireg (belzutifan)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/18/2021
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Welireg (belzutifan)
Von Hippel-Lindau (VHL) disease Indicated for treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery **Advanced Renal Cell Carcinoma (RCC)** Indicated for treatment of adult patients with advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI).

2 . Criteria

Product Name:Welireg	
Diagnosis	von Hippel-Lindau (VHL) disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WELIREG	BELZUTIFAN TAB 40 MG	21421020000320	Brand

Approval Criteria

1 - Diagnosis of von Hippel-Lindau (VHL) disease [A, 1]

AND

2 - Patient requires therapy for one of the following [A, 1] :

Renal cell carcinoma (RCC)

Central nervous system (CNS) hemangioblastoma

Pancreatic neuroendocrine tumor (pNET)

AND

3 - Patient does not require immediate surgery [A,1]

Product Name:Welireg	
Diagnosis	von Hippel-Lindau (VHL) disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WELIREG	BELZUTIFAN TAB 40 MG	21421020000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy [A, 1]

Product Name:Welireg	
Diagnosis	Advanced Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WELIREG	BELZUTIFAN TAB 40 MG	21421020000320	Brand

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - Disease has progressed after treatment with both of the following:

2.1 One of the following:

Programmed death receptor-1 (PD-1) inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)]

Programmed death-ligand 1 (PD-L1) inhibitor [e.g., Bavencio (avelumab), Imfinzi (durvalumab)]

AND

2.2 Vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) [e.g., Votrient (pazopanib), Inlyta (axitinib)]

Product Name:Welireg	
Diagnosis	Advanced Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WELIREG	BELZUTIFAN TAB 40 MG	21421020000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

The efficacy of WELIREG was evaluated in Study 004 (NCT03401788), an open-label clinical trial in 61 patients with VHL-associated RCC diagnosed based on a VHL germline alteration and with at least one measurable solid tumor localized to the kidney as defined by response evaluation criteria in solid tumors (RECIST) v1.1. Enrolled patients had other VHL-associated tumors including CNS hemangioblastomas and pNET. CNS hemangioblastomas and pNET in these patients were diagnosed based on the presence of at least one measurable solid tumor in brain/spine or pancreas, respectively, as defined by RECIST v1.1 and identified by IRC. The study excluded patients with metastatic disease. Patients received WELIREG 120 mg once daily until progression of disease or unacceptable toxicity. The study population characteristics were: median age 41 years [range 19-66 years], 3.3% age 65 or older; 53% male; 90% were White, 3.3% were Black or AfricanAmerican, 1.6% were Asian, and 1.6% were Native Hawaiian or other Pacific Islander; 82% had an ECOG PS of 0, 16% had an ECOG PS of 1, and 1.6% had an ECOG PS of 2; and 84% had VHL Type I Disease. The median diameter of RCC target lesions per central independent review committee (IRC) was 2.2 cm (range 1-6.1). Median time from initial radiographic diagnosis of VHL-associated RCC tumors that led to enrollment on Study 004 to the time of treatment with WELIREG was 17.9 months (range 2.8-96.7). Seventy- seven percent of patients had prior surgical procedures for RCC. The major efficacy endpoint for the treatment of VHL-associated RCC was overall response rate (ORR) measured by radiology assessment

using RECIST v1.1 as assessed by IRC. Additional efficacy endpoints included duration of response (DoR), and time to response (TTR).

4 . References

Welireg [Prescribing Information]. Merck & Co, Inc. Rathway, NJ. December 2023.

NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer V2.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed October 1, 2024.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-229035
Guideline Name	Xalkori (crizotinib) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xalkori (crizotinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)- or ROS1-positive as detected by an FDA-approved test. **Anaplastic Large Cell Lymphoma (ALCL)** Indicated for the treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. Limitations of use: The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL. **Inflammatory Myofibroblastic Tumor** Indicated for the treatment of adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive.

2 . Criteria

Product Name:Xalkori	
Diagnosis	Non-small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

2.1.2 One of the following:

2.1.2.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

Alecensa (alectinib)

Alunbrig (brugatinib)

OR

2.1.2.2 For continuation of therapy

OR

2.2 Patient has ROS1 rearrangements-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma (ALCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Diagnosis of systemic anaplastic large cell lymphoma (ALCL)

AND

2 - Disease is one of the following:

Relapsed

Refractory

AND

3 - Patient is 1 year of age or older

AND

4 - Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

2 - Disease is one of the following:

Unresectable

Recurrent

Refractory

AND

3 - Patient is 1 year of age or older

AND

4 - Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Xalkori	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Xalkori	
Diagnosis	Non-small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Both of the following:

2.1.1 Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

2.1.2 One of the following:

2.1.2.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

Alecensa (alectinib)

Alunbrig (brugatinib)

OR

2.1.2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

OR

2.2 Patient has ROS1 rearrangements-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma (ALCL)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of systemic anaplastic large cell lymphoma (ALCL)

AND

1.2 Disease is one of the following:

Relapsed

Refractory

AND

2 - Patient is 1 year of age or older

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

1.2 Disease is one of the following:

Unresectable

Recurrent

Refractory

AND

2 - Patient is 1 year of age or older

AND

3 - Submission of medical records (e.g., chart notes) confirming the patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

3 . References

Xalkori Prescribing Information. Pfizer Labs. New York, NY. September 2023.

The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed August 12, 2022.

4 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229037
Guideline Name	Xdemvy (lotilaner) PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xdemvy (lotilaner ophthalmic solution)
Demodex Blepharitis Indicated for the treatment of Demodex blepharitis.

2 . Criteria

Product Name:Xdemvy	
Approval Length	2 months [A, 3]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XDEMVY	LOTILANER OPHTH SOLN 0.25%	86106050002020	Brand

Approval Criteria

1 - Diagnosis of Demodex blepharitis

AND

2 - Patient exhibits one of the following signs of Demodex infestation [2]

Collarettes [B, 2]

Eyelid margin erythema

Eyelash anomalies (e.g., eyelash misdirection)

AND

3 - Patient is experiencing symptoms or architectural changes associated with Demodex infestation (e.g., burning, tearing, itching, foreign body sensation, eyelashes missing, eyelashes growing inward) [C, 3]

AND

4 - Trial and inadequate response to tea tree-oil [D-E, 3-4]

AND

5 - Prescribed by or in consultation with one of the following:

Ophthalmologist

Optometrist

Product Name:Xdemvy	
Approval Length	2 months [A, 3]

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XDEMVY	LOTILANER OPHTH SOLN 0.25%	86106050002020	Brand

Approval Criteria

1 - Diagnosis of Demodex blepharitis

AND

2 - Submission of medical records (e.g., chart notes) confirming that patient exhibits one of the following signs of Demodex infestation confirmed by slit lamp examination [F-H, 2, 7-9]

Collarettes [B, 2]

Eyelid margin erythema

Eyelash anomalies (e.g., eyelash misdirection)

AND

3 - Submission of medical records (e.g., chart notes) confirming that patient is experiencing symptoms or architectural changes associated with Demodex infestation (e.g., burning, tearing, itching, foreign body sensation, eyelashes missing, eyelashes growing inward) [C, 3]

AND

4 - Submission of medical records (e.g., chart notes) confirming trial and inadequate response (minimum 6 weeks) to tea tree-oil [D-E, I, 3-4, 10-11]

AND

5 - Symptoms persist despite practicing good eye-lid hygiene (e.g.,treatment with warm compress, eyelid cleansing, artificial tears, non-prescription tree-tea oil)

AND

6 - Prescribed by or in consultation with one of the following:

Ophthalmologist

Optometrist

3 . Definitions

Definition	Description
Collarettes	Solidified exudative excretions that form a cylindrical collar around the base of the eyelash follicle - are the pathognomonic sign of Demodex blepharitis [2].

4 . Endnotes

Xdemvy kills the "adult" mite. However, the product does not kill the eggs. The life cycle of the mite is about 27 days. The eggs will hatch. If stop prior to this, those 2nd generation mites won't be killed. Need 2 or 3 generations to eradicate mites and eggs that will hatch. Multiple courses of treatment may be necessary. The physician would re-evaluate patient after 3 months not 6 weeks. Goal of treatment is to get to a threshold below where the patient is not experiencing symptoms. Mites live on clothes, pillowcases, sheets so re-infection possible. For this reason, difficult to eradicate to where there are "zero" mites.[3]

Collarettes are often referred to in the literature as cylindrical dandruff (CD), sleeves, cuffs, crusting, or lash debris [2]

If Demodex is not overpopulated and not causing problem can leave it alone; if burning, tearing, itching, foreign body sensation, etc. or architectural changes in lid, eyelashes missing, eyelashes grow inward (scratching cornea, scarring), consider treating the Demodex blepharitis [3]

Tea Tree Oil has been the standard treatment. It suppresses the mite and tricks the mite into coming out of its buried status in the skin. Mites are nocturnal, so they are embedded during the day and come out at night. Tea tree oil is available in shampoos, soaps, and

specific ocular products (e.g., Cliradex 10% wipes or foam) and are available OTC. Cliradex 50% is available and is used as an in office procedure since higher concentrations can be very irritating to the eyes and skin [3]

In general, topical formulations containing tea tree oil were reported to be effective in reducing the number of Demodex mites on eyelashes. Other emerging treatment options include anti-parasitic drugs and IPL, but there is currently limited high-quality evidence to ascertain the efficacy of these treatments for ocular Demodex with any certainty. [4]

Because patients with Demodex blepharitis can often be asymptomatic, it is important to begin every clinical evaluation at the slit lamp with the patient's eyes closed for a better view of the superior lid and lash margin, looking for the presence of collarettes. [7]

Slit-lamp examination is all an eye care provider needs to do to make the diagnosis [8]

Several conditions such as rosacea, MGD, and DED often occur with DB [52–55]. Since clinically these conditions are often very similar, the panel concurred that DB is frequently underdiagnosed or misdiagnosed. The consensus, therefore, was that all patients presenting for an eye exam should be evaluated for collarettes, especially those with lid abnormalities or those not responding to treatment for DED or MGD. DEPTH panellists shared that slit lamp examination with the patient looking down is simple and easy to incorporate into routine exams. [9]

It has been recommended to use tea tree oil treatments for at least two Demodex mite life cycles (i.e. approximately six weeks) in order to ensure adequate killing of the parasite [10]

5 . References

Xdemvy Prescribing Information. Tarsus Pharmaceuticals, Inc. Irvine, CA. July 2023.

Rhee, M., Yeu, E., Barnett., M., et al. Demodex Blepharitis: A Comprehensive Review of the Disease, Current Management, and Emerging Therapies. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10351901/. Accessed October 26, 2023.

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ClinicalTrials.gov. Safety and Efficacy of TP-03 for the Treatment of Demodex Blepharitis (Saturn-1). Available at: https://www.clinicaltrials.gov/study/NCT04784091?cond=demodex%20blepharitis&rank=4. Accessed October 26, 2023.

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Odell, L., and Garlich, J. A Primer on Demadex Blepharitis. Available at: https://modernod.com/articles/2020-nov-dec/a-primer-on-idemodexi-blepharitis?c4src=article:infinite-scroll. Accessed February 23, 2024.

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Ayres, B., Donnenfeld, E., Farid, M.. et al. Clinical diagnosis and management of Demodex blepharitis: the Demodex Expert Panel on Treatment and Eyelid Health (DEPTH). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10564779/. Accessed February 23, 2024.

Savla, K., Le, J., Pucker, A., et al. Tea Tree Oil for Demadex blepharitis. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7388771/. Accessed February 23, 2024.

Cheng AM, Sheha H, Tseng SC. Recent advances on ocular Demodex infestation. Current Opinion in Ophthalmology 2015;26(4):295-300.

6 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229039
Guideline Name	Xeljanz, Xeljanz XR (tofacitinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xeljanz (tofacitinib) tablets, Xeljanz XR (tofacitinib) extended-release tablets
Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis, who have an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Drug Name: Xeljanz (tofacitinib) tablets and oral solution

Polyarticular Course Juvenile Idiopathic Arthritis Indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

2 . Criteria

Product Name:Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

methotrexate

leflunomide

sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand

XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT)	66603065102020	Brand

Approval Criteria

1 - Diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

leflunomide

methotrexate

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, etanercept)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT)	66603065102020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [5]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topi cal or inhaled corticosteroids, and/or low stable dosages of oral cortic osteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 6]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Xeljanz tablets or Xeljanz XR tablets

Diagnosis	Ulcerative Colitis (UC)
Approval Length	4 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT)	66603065107550	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, ESR, CRP)

Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [7, 8]:

6-mercaptopurine

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

Azathioprine

Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, golimumab)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topi cal or inhaled corticosteroids, and/or low stable dosages of oral cortic osteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand

XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT)	66603065107550	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 7, 8]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

AND

2 - Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Endnotes

Initial approval length of 4 months based on dosing recommendation provided in the labeling of Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily for at least 8 weeks, followed by Xeljanz 5 mg once or twice daily, 10 mg twice daily, or Xeljanz XR 11 mg once daily depending on therapeutic response. Xeljanz should be discontinued after 16 weeks (4 months) of treatment with Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily if adequate therapeutic response is not achieved.

4 . References

Xeljanz, Xeljanz XR Prescribing Information. Pfizer, Inc. New York, NY. May 2024.

Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.

Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.

Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.

Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019;114:384–413.

Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229041
Guideline Name	Xenazine (tetrabenazine)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xenazine (tetrabenazine)
Chorea associated with Huntington's disease Indicated for the treatment of chorea associated with Huntington's disease. **<u>Off Label Uses:</u> Hyperkinetic movement disorders in tardive dyskinesia and Tourette's syndrome [2-5]** Has shown effectiveness in the treatment of hyperkinetic movement disorders (hyperkinesias) characterized by abnormal involuntary movements seen in tardive dyskinesia (TD), or issues such as tics (eye blink, shouting obscenities or profanities, etc.) observed in Tourette's syndrome (TS).

2 . Criteria

Product Name:Brand Xenazine

Diagnosis	Chorea associated with Huntington's disease
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

AND

2 - Prescribed by or in consultation with a neurologist [C]

AND

3 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name:Generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

AND

2 - Prescribed by or in consultation with a neurologist [C]

Product Name:Brand Xenazine, Generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Brand Xenazine	
Diagnosis	Tourette's syndrome (Off-label)
Approval Length	3 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome [2, 4]

AND

2 - Trial and failure, contraindication, or intolerance to a minimum 30 day supply of Haldol (haloperidol)

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

AND

4 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name:Generic tetrabenazine	
Diagnosis	Tourette's syndrome (Off-label)
Approval Length	3 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome [2, 4]

AND

2 - Trial and failure, contraindication, or intolerance to a minimum 30 day supply of Haldol (haloperidol)

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Product Name:Brand Xenazine, Generic tetrabenazine	
Diagnosis	Tourette's syndrome (Off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Brand Xenazine	
Diagnosis	Tardive dyskinesia (Off-label)

Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand

Approval Criteria

1 - Diagnosis of tardive dyskinesia [3, 4]

AND

2 - One of the following [A, 5]:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

AND

4 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name:Generic tetrabenazine	
Diagnosis	Tardive dyskinesia (Off-label)
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Diagnosis of tardive dyskinesia [3, 4]

AND

2 - One of the following [A, 5]:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Product Name:Brand Xenazine, Generic tetrabenazine	
Diagnosis	Tardive dyskinesia (Off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

Verified with consultant for a previous medication (Ingrezza [valbenazine]) that dose reduction, tapering, or discontinuation of the offending medication is considered first-line treatment for tardive dyskinesia. [5]

Authorization period is based on the pivotal study duration of 12 weeks. [1]

Ensures the requirement for proper diagnosing and quantifying an adequate chorea score (total maximal chorea score of greater than or equal to 10 (moderate to severe chorea) from the subscale of the Unified Huntington's Disease Rating Scale (UHDRS). Note that the pivotal trial that established efficacy of tetrabenazine included patients with a total maximal chorea of greater than or equal to 10. [1]

4 . References

Xenazine Prescribing Information. Lundbeck. Deerfield, IL. November 2019.

Sweet RD, Brauun R, Shapiro E, Shapiro AK. Presynaptic catecholamine antagonists as treatment for Tourette syndrome. Effects of alpha methyl para tyrosine and tetrabenazine. Arch Gen Psych. 1974;31:857-861.

Kazamatsuri H, Chien C-P, Cole J. Treatment of Tardive Dyskinesia: clinical efficacy of a dopamine-depleting agent, tetrabenazine. Arch Gen Psychiat. 1972;27:95-99.

Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at: https://www.micromedexsolutions.com. Accessed April 1, 2021.

Per clinical consult with psychiatrist regarding Ingrezza (valbenazine), June 9, 2017.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228749
Guideline Name	Xeomin (incobotulinumtoxinA)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xeomin (incobotulinumtoxinA)
Blepharospasm Indicated for the treatment of blepharospasm in adults. **Cervical Dystonia** Indicated for the treatment of cervical dystonia in adults. **Chronic Sialorrhea** Indicated for the treatment of chronic sialorrhea in patients 2 years of age and older. **Adult Upper Limb Spasticity** Indicated for the treatment of upper limb spasticity in adults. **Pediatric Upper Limb Spasticity** Indicated for the treatment of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy. **Cosmetic Uses [Non-approvable Use]** Is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults. *Note: Use of Xeomin for the improvement in the appearance of glabellar lines is excluded, as this is considered a cosmetic use.

2 . Criteria

Product Name:Xeomin	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 50 UNIT	74400020202120	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 100 UNIT	74400020202130	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR IM INJ 200 UNIT	74400020202140	Brand

Approval Criteria

1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis) [1]

Product Name:Xeomin	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 50 UNIT	74400020202120	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 100 UNIT	74400020202130	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR IM INJ 200 UNIT	74400020202140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have elapsed or will have elapsed since the last treatment [1]

Product Name:Xeomin	
Diagnosis	Blepharospasm
Approval Length	3 months [1, B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 50 UNIT	74400020202120	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 100 UNIT	74400020202130	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR IM INJ 200 UNIT	74400020202140	Brand

Approval Criteria

1 - Diagnosis of blepharospasm

Product Name:Xeomin	
Diagnosis	Blepharospasm
Approval Length	3 months [1, 4, C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 50 UNIT	74400020202120	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 100 UNIT	74400020202130	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR IM INJ 200 UNIT	74400020202140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have elapsed or will have elapsed since the last treatment [C]

Product Name:Xeomin	
Diagnosis	Upper Limb Spasticity
Approval Length	3 months [1, 3]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 50 UNIT	74400020202120	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 100 UNIT	74400020202130	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR IM INJ 200 UNIT	74400020202140	Brand

Approval Criteria

1 - Diagnosis of upper limb spasticity [1]

AND

2 - Patient is 2 years of age or older

Product Name:Xeomin	
Diagnosis	Upper Limb Spasticity
Approval Length	3 months [1, 3, D]

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 50 UNIT	74400020202120	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 100 UNIT	74400020202130	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR IM INJ 200 UNIT	74400020202140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have elapsed or will have elapsed since the last treatment [D]

Product Name:Xeomin	
Diagnosis	Chronic Sialorrhea
Approval Length	3 months [1, D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 50 UNIT	74400020202120	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 100 UNIT	74400020202130	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR IM INJ 200 UNIT	74400020202140	Brand

Approval Criteria

1 - Diagnosis of chronic sialorrhea

AND

2 - Patient is 2 years of age or older

Product Name:Xeomin	
Diagnosis	Chronic Sialorrhea
Approval Length	3 months [1, D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 50 UNIT	74400020202120	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 100 UNIT	74400020202130	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR IM INJ 200 UNIT	74400020202140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 4 months have elapsed or will have elapsed since the last treatment [E]

Product Name:Xeomin	
Diagnosis	Cosmetic Use
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 50 UNIT	74400020202120	Brand
XEOMIN	INCOBOTULINUMTOXINA FOR INJ 100 UNIT	74400020202130	Brand

XEOMIN	INCOBOTULINUMTOXINA FOR IM INJ 200 UNIT	74400020202140	Brand

Approval Criteria

1 - Requests for coverage of any Xeomin product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only.

3 . Endnotes

In a randomized, double-blind, active-controlled, parallel group study, 463 patients with a documented stable therapeutic response to Botox as a result of the last two consecutive injection sessions directly prior to trial entry (70 to 300 Units) were included. Patients in the study received IM injections of 70 to 300 Units of Xeomin or Botox, based on the previous two consecutive doses of Botox prior to study entry. [2]

The total initial dose of Xeomin in both eyes should not exceed 50 Units (25 Units/eye). [1]

The median onset of treatment effect with incobotulinumtoxinA was 4 days (range, 0 to 30 days), time to waning of treatment effect was 6 weeks (range 1 to 15 weeks), and duration of treatment effect was 10.6 weeks (range, 6.1 to 19.1 weeks). [4]

The typical duration of effect of each treatment is up to 12-16 weeks; however, the duration of effect may vary in individual patients. [1]

The timing for repeat treatment of chronic sialorrhea should be determined based on the actual clinical need of the individual patient, and no sooner than every 16 weeks (4 months). [1]

4 . References

Xeomin Prescribing Information. Merz Pharmaceuticals, LLC. Raleigh, NC. July 2024.

Benecke R, Jost WH, Kanovsky P, Ruzicka E, Comes G, Grafe S. A new botulinum toxin type A free of complexing proteins for treatment of cervical dystonia. Neurology. 2005;64:1949-1951.

Kanovsky P, Slawek J, Denes Z, et al. Efficacy and safety of treatment with incobotulinum toxin A (botulinum neurotoxin type A free from complexing proteins; NT 201) in post-stroke upper limb spasticity. J Rehabil Med 2011; 43(6):486-492.

Jankovic J, Comella C, Hanschmann A, et al. Efficacy and safety of incobotulinumtoxinA (NT 201, Xeomin) in the treatment of blepharospasm-a randomized trial. Mov Disord 2011; 26(8):1521-1528.

Prior Authorization Guideline

Guideline ID	GL-233197
Guideline Name	Xermelo (telotristat ethyl)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	4/26/2017
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Xermelo (telotristat ethyl)
Carcinoid syndrome diarrhea Indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.

2 . Criteria

Product Name:Xermelo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XERMELO	TELOTRISTAT ETIPRATE TAB 250 MG (TELOTRISTAT ETHYL EQUIV)	52570075100330	Brand

Approval Criteria

1 - Diagnosis of carcinoid syndrome diarrhea

AND

2 - Diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months [A,B,1-6]

AND

3 - Used in combination with SSA therapy

AND

4 - Prescribed by or in consultation with one of the following:

Oncologist

Endocrinologist

Gastroenterologist

Product Name:Xermelo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XERMELO	TELOTRISTAT ETIPRATE TAB 250 MG (TELOTRISTAT ETHYL EQUIV)	52570075100330	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy [C,D,6,7]

AND

2 - Medication will continue to be used in combination with SSA therapy

3 . Endnotes

In the pivotal trial population, patients were experiencing 4 to 12 bowel movements (BM) daily despite the use of SSA therapy (e.g., octreotide, lanreotide) at a stable dose for at least 3 months [1].

Diarrhea is often chronic with carcinoid syndrome, in about 80% of cases, and can occur up to 30 times a day. SSA therapy provides symptomatic relief in 50 to 70% of patients. [2].

In an open label extension of the TELESTAR trial, bowel movement (BM) reductions were consistent with the results from the double-blind trial period [6].

Long-term safety and efficacy were demonstrated in the open label extension study. Throughout the up to 6 years of follow up, patients experienced symptomatic relief but no new safety concerns [7].

4 . References

Xermelo Prescribing Information. Lexicon Pharmaceuticals, Inc. The Woodlands, TX. September 2022.

Pandit S, Annamaraju P, Bhusal K. Carcinoid syndrome. StatPearls [Internet]. Treasure Island (FL): Stat Pearls Publishing; 2024 Jan. Available at: https://www.ncbi.nlm.nih.gov/books/NBK448096. Accessed October 13, 2024.

Eriksson B, Klöppel G, Krenning E, et al. Consensus guidelines for the management of patients with digestive neuroendocrine tumors – well-differentiated jejunal-ileal tumor/carcinoma. Neuroendocrinology 2008;87:8-19.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Neuroendocrine and Adrenal Tumors v2.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/PDF/neuroendocrine.pdf. Accessed October 9, 2024.

Kulke MH, Anthony LB, Bushnell DL, et al. NANETS Treatment Guidelines: Well differentiated neuroendocrine tumors of the stomach and pancreas. Pancreas. 2010 Aug; 39(6): 735–752. doi: 10.1097/MPA.0b013e3181ebb168.

Kulke MH, Horsch D, Caplin ME, et al. Telotristat ethyl, a tryptophan hydroxylase inhibitor for the treatment of carcinoid syndrome. J Clin Oncol. 2017 Jan;35(1):14-23. Epub 2016 Oct 28.

Horsch D, Anthony L, Gross DJ, et al. Long-term treatment with telotristat ethyl in patients with carcinoid syndrome symptoms: Results from the TELEPATH study. Neuroendocrinology. 2022 Mar;112(3):298-309.

5 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-229044
Guideline Name	Xgeva (denosumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xgeva (denosumab)
Multiple myeloma and Bone metastasis from solid tumors Indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. **Giant cell tumor of bone** Indicated for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. **Hypercalcemia of malignancy** Indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

2 . Criteria

Product Name:Xgeva	
Diagnosis	Skeletal prevention in multiple myeloma and bone metastasis from solid tumors (BMST)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XGEVA	DENOSUMAB INJ 120 MG/1.7ML	30044530002030	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of multiple myeloma

AND

1.1.2 Trial and failure, contraindication (e.g., renal insufficiency), or intolerance, to one intravenous bisphosphonate (e.g., zoledronic acid) [9]

OR

1.2 Both of the following:

1.2.1 Diagnosis of solid tumors (e.g., breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) [1-5]

AND

1.2.2 Documented evidence of one or more metastatic bone lesions

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Xgeva

Diagnosis	Giant cell tumor of bone
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XGEVA	DENOSUMAB INJ 120 MG/1.7ML	30044530002030	Brand

Approval Criteria

1 - Diagnosis of giant cell tumor of bone

AND

2 - One of the following:

2.1 Tumor is unresectable

OR

2.2 Surgical resection is likely to result in severe morbidity

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Xgeva	
Diagnosis	Giant cell tumor of bone
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XGEVA	DENOSUMAB INJ 120 MG/1.7ML	30044530002030	Brand

Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Xgeva therapy [A]	
Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Xgeva	
Diagnosis	Hypercalcemia of malignancy
Approval Length	2 Month [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XGEVA	DENOSUMAB INJ 120 MG/1.7ML	30044530002030	Brand

Approval Criteria

1 - Diagnosis of hypercalcemia of malignancy

AND

2 - Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (e.g., pamidronate, zoledronic acid) [6, 7]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name:Xgeva	
Diagnosis	Hypercalcemia of malignancy
Approval Length	2 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XGEVA	DENOSUMAB INJ 120 MG/1.7ML	30044530002030	Brand

Approval Criteria **1** - Documentation of positive clinical response to Xgeva therapy	
Notes	If patient meets criteria above, please approve at GPI-12.

3 . Endnotes

Xgeva should be continued until disease progression in responding patients. [8]

Median time on the study for the treatment of hypercalcemia of malignancy was 56 days. [6]

4 . References

Xgeva prescribing information. Amgen Inc. Thousand Oaks, CA. June 2020.

Stopeck AT, Lipton A, Body JJ, et al. Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer: a randomized, double-blind study. J Clin Oncol. 2010;28:5132-39.

Fizazi K, Carducci MA, Smith MR, et al. Denosumab versus zoledronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: a randomised, double-blind study. Lancet. 2011;377(9768):813-22.

Henry DH, Costa L, Goldwasser F, et al. Randomized, double-blind study of denosumab versus zoledronic acid in the treatment of bone metastases in patients with advanced cancer (excluding breast and prostate cancer) or multiple myeloma. J Clin Oncol. 2011;29(9):1125-32.

Lipton A, Fizazi K, Stopeck AT, Henry DH, et al. Superiority of denosumab to zoledronic acid for prevention of skeletal-related events: a combined analysis of 3 pivotal, randomised, phase 3 trials. Eur J Cancer. 2012;48(16):3082-92.

Hu MI, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocinol Metab. 2014;99(9):3144-52.

Stewart AF. Hypercalcemia associated with cancer. N Engl J Med. 2005; 352(4):379-9.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Bone Cancer v1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed June 9, 2021.

National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 2, 2022.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229045
Guideline Name	Xiaflex (collagenase clostridium histolyticum)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xiaflex (collagenase clostridium histolyticum)
Dupuytren's Contracture Indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord. **Peyronie's Disease** Indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

2 . Criteria

Product Name:Xiaflex	
Diagnosis	Dupuytren’s contracture
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIAFLEX	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM FOR INJ 0.9 MG	99350035002120	Brand

Approval Criteria

1 - Diagnosis of Dupuytren's contracture with a palpable cord

AND

2 - Patient has a positive "table top test" (defined as the inability to simultaneously place the affected finger and palm flat against a table top) [A]

AND

3 - Patient has a documented contracture of at least 20 degrees flexion for a metacarpophalangeal joint or a proximal interphalangeal joint [B]

AND

4 - Patient has a flexion deformity that results in functional limitations

Product Name:Xiaflex	
Diagnosis	Peyronie's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIAFLEX	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM FOR INJ 0.9 MG	99350035002120	Brand

Approval Criteria

1 - Diagnosis of Peyronie’s disease

AND

2 - Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy [C]

AND

3 - The plaques do not involve the penile urethra

AND

4 - Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse) [C]

Product Name:Xiaflex	
Diagnosis	Peyronie’s disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIAFLEX	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM FOR INJ 0.9 MG	99350035002120	Brand

Approval Criteria

1 - Diagnosis of Peyronie’s disease

AND

2 - Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

AND

3 - The plaques do not involve the penile urethra

AND

4 - Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse)

AND

5 - Patient has a new plaque that results in a curvature deformity

3 . Endnotes

Dupuytren's disease diagnosis can include a table top test to assess the severity of the disease. When a patient is unable to place his or her palm and the affected finger flat on the table, the test can help diagnosis Dupuytren's disease. [1]

Dupuytren's disease is associated with joint contracture. Xiaflex was studied in a patient population with joint contracture of at least 20 degrees. Evidence does not support any benefit in patients with joint contracture less than 20 degrees. Our program requires that the patient has a flexion deformity that results in functional limitations to protect against cosmetic use. [1]

Peyronie's disease is characterized by a curvature deformity. Xiaflex was studied in a patient population with a curvature deformity of at least 30 degrees. Evidence does not support any benefit in patients with a curvature deformity less than 30 degrees. To prevent cosmetic use, patients must also have a curvature deformity that results in pain. [1]

4 . References

Xiaflex Prescribing Information. Endo Pharmaceuticals, Inc. Malvern, PA. July 2022.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228751
Guideline Name	Xifaxan (rifaximin) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xifaxan (rifaximin)
Travelers' Diarrhea 200mg is indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adults and pediatric patients 12 years of age and older. Limitations of use: Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli. [A] **Prophylaxis of Hepatic Encephalopathy Recurrence** 550 mg is indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults. In the trials of Xifaxan for HE, 91% of patients were using lactulose concomitantly. Differences in the treatment effect of those patients not using lactulose concomitantly could not be assessed. Xifaxan has not been studied in patients with MELD (Model for End-Stage Liver Disease) score greater than 25, and only 8.6% of patients in the controlled trial had MELD scores over 19. There is increased systemic exposure in patients with more severe hepatic dysfunction. **Irritable Bowel Syndrome with Diarrhea** 550 mg is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults. **Off Label Uses: Treatment of Hepatic Encephalopathy** Used for the treatment of hepatic encephalopathy. [4, 5, 22]

Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)
Has been used for the treatment of small intestinal bacterial overgrowth. [7, 8, 10, 13]

2 . Criteria

Product Name:Xifaxan 200 mg tablets*	
Diagnosis	Travelers' Diarrhea (TD)
Approval Length	1 Time only
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand

Approval Criteria

1 - Diagnosis of travelers' diarrhea (TD)

AND

2 - Disease is moderate to severe [D, 9]

AND

3 - One of the following:

3.1 Trial and failure of one of the following: [2, 3, D, E]

Zithromax (azithromycin)

Cipro (ciprofloxacin)

Levaquin (levofloxacin)

Ofloxacin

OR

3.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

Zithromax (azithromycin)

Cipro (ciprofloxacin)

Levaquin (levofloxacin)

Ofloxacin

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name:Xifaxan 200 mg tablets*	
Diagnosis	Travelers' Diarrhea (TD)
Approval Length	1 Time only
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of travelers' diarrhea (TD)

AND

2 - Disease is moderate to severe [D, 9]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Trial and failure to two of the following: [2, 3, D, E]

Zithromax (azithromycin)

Cipro (ciprofloxacin)

Levaquin (levofloxacin)

Ofloxacin

OR

3.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

Zithromax (azithromycin)

Cipro (ciprofloxacin)

Levaquin (levofloxacin)

Ofloxacin

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name:Xifaxan	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Diagnosis of Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)

AND

2 - One of the following:

2.1 Trial and failure of two of the following antibiotics: [5, 16-21]

Neomycin

Augmentin (amoxicillin/clavulanic acid)

Cipro (ciprofloxacin)

Bactrim (trimethoprim-sulfamethoxazole)

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline

Flagyl (metronidazole)

Keflex (cephalexin)

OR

2.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

Neomycin

Augmentin (amoxicillin/clavulanic acid)

Cipro (ciprofloxacin)

Bactrim (trimethoprim-sulfamethoxazole)

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline

Flagyl (metronidazole)

Keflex (cephalexin)

Product Name:Xifaxan	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., resolution of symptoms or relapse with Xifaxan discontinuation) [B]

AND

2 - One of the following:

2.1 Trial and failure of two of the following antibiotics: [5, 16-21]

Neomycin

Augmentin (amoxicillin/clavulanic acid)

Cipro (ciprofloxacin)

Bactrim (trimethoprim-sulfamethoxazole)

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline

Flagyl (metronidazole)

Keflex (cephalexin)

OR

2.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

Neomycin

Augmentin (amoxicillin/clavulanic acid)

Cipro (ciprofloxacin)

Bactrim (trimethoprim-sulfamethoxazole)

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline

Flagyl (metronidazole)

Keflex (cephalexin)

Product Name:Xifaxan 200 mg tablets*	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Trial and failure of three of the following antibiotics: [5, 16-21]

Neomycin

Augmentin (amoxicillin/clavulanic acid)

Cipro (ciprofloxacin)

Bactrim (trimethoprim-sulfamethoxazole)

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline

Flagyl (metronidazole)

Keflex (cephalexin)

OR

2.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

Neomycin

Augmentin (amoxicillin/clavulanic acid)

Cipro (ciprofloxacin)

Bactrim (trimethoprim-sulfamethoxazole)

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline

Flagyl (metronidazole)

Keflex (cephalexin)

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name:Xifaxan 550 mg tablets*	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	2 Weeks [1, I]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) [F]

AND

2 - Patient is 18 years of age or older [L]

AND

3 - Trial and failure, contraindication, or intolerance to both of the following:

A Tricyclic Antidepressant (e.g., amitriptyline, nortriptyline)

Viberzi

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name:Xifaxan 550 mg tablets*	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	2 Weeks [1, I]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Symptoms of Irritable Bowel Syndrome continue to persist [G, H]

AND

2 - Patient demonstrates positive clinical response to therapy as evidenced by both of the following: [1]

Improvement in abdominal pain

Reduction in the Bristol Stool Scale

AND

3 - Trial and failure, contraindication, or intolerance to both of the following:

A Tricyclic Antidepressant (e.g., amitriptyline, nortriptyline)

Viberzi

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name:Xifaxan 550 mg tablets*	
Diagnosis	Prophylaxis of Hepatic Encephalopathy (HE) Recurrence
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Used for prophylaxis of hepatic encephalopathy (HE) recurrence

AND

2 - Patient is 18 years of age or older [L]

AND

3 - One of the following: [J, 22]

3.1 Both of the following:

3.1.1 Used as add-on therapy to lactulose

AND

3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

3.2 History of contraindication or intolerance to lactulose

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name:Xifaxan 550 mg tablets*	
Diagnosis	Prophylaxis of Hepatic Encephalopathy (HE) Recurrence
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy [M, 27, 28]

AND

2 - One of the following: [J, 22]

2.1 Both of the following:

2.1.1 Used as add-on therapy to lactulose

AND

2.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

2.2 History of contraindication or intolerance to lactulose

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name:Xifaxan	
Diagnosis	Treatment of Hepatic Encephalopathy (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Used for the treatment of hepatic encephalopathy (HE) [5, K]

AND

2 - Patient is 18 years of age or older [L]

AND

3 - One of the following: [22, K]

3.1 Both of the following:

3.1.1 Used as add-on therapy to lactulose

AND

3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

3.2 History of contraindication or intolerance to lactulose

Product Name:Xifaxan 200 mg tablets*	
Diagnosis	Treatment of Hepatic Encephalopathy (Off-Label)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming used for the treatment of hepatic encephalopathy (HE) [5, K]

AND **2** - Patient is 18 years of age or older [L] **AND** **3** - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [22, K] **3.1** Both of the following: **3.1.1** Used as add-on therapy to lactulose **AND** **3.1.2** Patient is unable to achieve an optimal clinical response with lactulose monotherapy **OR** **3.2** History of contraindication or intolerance to lactulose	
Notes	Note: *If patient meets criteria above, please approve at GPI-14.

3 . Endnotes

Antibiotic treatment should be avoided in diarrhea caused by enterohemorrhagic E. coli. [6]

The main goals in the treatment of SBBO are 1) treatment of underlying small intestinal abnormality, when possible; 2) concentration on long-term antibiotic therapy when surgical management is not feasible; 3) adjunctive treatment of dysmotility, such as a prokinetic agent; and 4) nutritional support, particularly in patients with weight loss or vitamin deficiency. [7]

In most patients, a single course of treatment (10 days) markedly improves symptoms, and patients may remain free of symptoms for months. In others, symptoms recur quickly, and acceptable results can only be obtained with cyclic treatment (1 of every 4 weeks). In still others, continuous treatment may be needed for 1 to 2 months. If the antimicrobial agent is effective, a resolution or marked diminution of symptoms will be notable within

several days of initiating therapy. Diarrhea and steatorrhea will decrease, and cobalamin malabsorption will be corrected. [7]

According to the Centers for Disease Control and Prevention's Yellow Book, antibiotics may be used to treat cases of moderate to severe travelers' diarrhea. Fluoroquinolones including, but not limited to, ciprofloxacin and levofloxacin, are considered first line agents in the treatment of Traveler's Diarrhea (TD). Azithromycin is also considered a first line agent for treatment of TD and is especially efficacious in the pediatric population. The overall usefulness of Rifaximin for empiric self-treatment remains to be determined as Rifaximin has only been shown to be efficacious in patients with noninvasive strains of E. coli. [9]

Levofloxacin, ofloxacin and ciprofloxacin have all been shown to be highly effective in the treatment and prevention of Travelers' Diarrhea and should be considered first-line therapy options for this indication. [11]

In the TARGET I, II and III pivotal trials, Irritable Bowel Syndrome was diagnosed using the ROME II diagnostic criteria. According to the ROME-II criteria, an IBS-D diagnosis requires at least 12 consecutive weeks in the previous 12 months of abdominal discomfort or pain that has two out of the three following features: relieved with defecation; and/or onset associated with a change in frequency of stool; and/or onset associated with a change in appearance of stool [12, 14]

In the TARGET III pivotal trial, a total of 636 responders (59%) required retreatment. The median time to recurrence for patients who experienced initial response was 10 weeks (range from 6 to 24 weeks) [14]

According to the ROME-IV criteria, recurrent signs and symptoms of IBS-D include the following: a return of abdominal pain or mushy/watery stool consistency for at least 3 weeks during a 4-week follow-up period. [15]

The recommended dose of Xifaxan for IBS-D is one 550 mg tablet taken orally three times a day for 14 days. [1]

The American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL) recommend rifaximin as an effective add-on therapy to lactulose for prevention of over hepatic encephalopathy with strength of recommendation 1A. No solid data support the use of rifaximin alone. [22]

Rifaximin has been used for the treatment of HE in a number of trials comparing it with placebo, other antibiotics, nonabsorable disaccharides, and in dose-ranging studies. These trials showed effect of rifaximin that was equivalent or superior to the compared agents with good tolerability. No solid data support the use of rifaximin alone. [22]

A minimum age requirement that aligns with the prescribing information was added for prophylaxis and treatment of hepatic encephalopathy and IBS-D to prevent misuse of Xifaxan in pediatrics. The same age requirement was not added for traveler's diarrhea or SBBO/SIBO due to the patient population (e.g., pediatrics) that Xifaxan was studied in. [1, 8, 10, 13, 26]

The risk of a breakthrough episode of hepatic encephalopathy (HE) in patients who recently had history of recurrent overt HE was reduced while taking Xifaxan. Additionally, patients on Xifaxan achieved full resolution of HE, so there is benefit with long-term use of Xifaxan for the prophylaxis of HE. [27, 28]

4 . References

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Prior Authorization Guideline

Guideline ID	GL-228590
Guideline Name	Xiidra (lifitegrast)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xiidra (lifitegrast)
Dry eye disease Indicated for the treatment of the signs and symptoms of dry eye disease (DED).

2 . Criteria

Product Name:Xiidra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIIDRA	LIFITEGRAST OPHTH SOLN 5%	86734050002020	Brand

Approval Criteria

1 - Diagnosis of dry eye disease

Product Name:Xiidra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIIDRA	LIFITEGRAST OPHTH SOLN 5%	86734050002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

3 . Endnotes

As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (i.e., emulsions, gels, and ointments can be used). Topical cyclosporine, topical corticosteroids, topical lifitegrast, systemic omega-3 fatty acid supplements, punctual plugs and spectacle side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management. [2]

4 . References

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Prior Authorization Guideline

Guideline ID	GL-229047
Guideline Name	Xolair (omalizumab)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xolair (omalizumab)
Allergic Asthma Indicated for adults and pediatric patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Limitations of Use: Xolair is not indicated for treatment of other allergic conditions. Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus. **Chronic Spontaneous Urticaria (CSU)** Indicated for the treatment of adults and adolescents 12 years of age and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment. Limitations of Use: Xolair is not indicated for treatment of other forms of urticaria. **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** Indicated for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids. **IgE-Mediated Food Allergy** Indicated for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy. XOLAIR is to be used

in conjunction with food allergen avoidance. Limitations of Use: XOLAIR is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

2 . Criteria

Product Name:Xolair	
Diagnosis	Allergic Asthma
Approval Length	6 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Diagnosis of moderate to severe persistent allergic asthma [1, 2]

AND

2 - Positive skin test or in vitro reactivity to a perennial aeroallergen [1, D]

AND

3 - One of the following:

3.1 All of the following:

3.1.1 Patient is 6 years of age or older but less than 12 years of age

AND

3.1.2 Pre-treatment serum immunoglobulin (Ig)E level between 30 to 1300 IU/mL

AND

3.1.3 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications [3]:

3.1.3.1 Both of the following:

Medium-dose inhaled corticosteroid (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day)

Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

3.1.3.2 One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg])

OR

3.2 All of the following:

3.2.1 Patient is 12 years of age or older

AND

3.2.2 Pre-treatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL

AND

3.2.3 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications [3]:

3.2.3.1 Both of the following:

High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)

Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

3.2.3.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg])

AND

4 - Prescribed by or in consultation with one of the following: [G]

Pulmonologist

Allergist/Immunologist

Product Name:Xolair	
Diagnosis	Allergic Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications [3]

AND

3 - Prescribed by or in consultation with one of the following: [G]

Pulmonologist

Allergist/immunologist

Product Name:Xolair	
Diagnosis	Chronic Spontaneous Urticaria (CSU)
Approval Length	3 months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Diagnosis of chronic spontaneous urticaria [1]

AND

2 - Patient is 12 years of age or older

AND

3 - Persistent symptoms (itching and hives) for at least 4 consecutive weeks despite titrating to an optimal dose with a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines

AND

4 - Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines

AND

5 - Patient has tried and had an inadequate response or intolerance at least TWO of the following additional therapies: [6, 7]

Doxepin

H1 antihistamine

H2 antagonist (e.g., famotidine, cimetidine)

Hydroxyzine

Leukotriene receptor antagonist (e.g., montelukast)

AND

6 - Prescribed by or in consultation with one of the following:

Allergist/immunologist

Dermatologist

Product Name:Xolair	
Diagnosis	Chronic Spontaneous Urticaria (CSU)
Approval Length	6 months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand

XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment

AND

2 - Patient has experienced at least one of the following:

Reduction in itching severity from baseline

Reduction in the number of hives from baseline

Product Name:Xolair	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand

XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)

AND

2 - Patient is 18 years of age or older

AND

3 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [8, 9]

AND

4 - Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) [H]

AND

5 - Prescribed by or in consultation with one of the following:

Allergist/Immunologist

Otolaryngologist

Pulmonologist

Product Name:Xolair	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NCS; 0-3 scale])

AND

2 - Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) [H]

AND

3 - Prescribed by or in consultation with one of the following:

Allergist/Immunologist

Otolaryngologist

Pulmonologist

Product Name:Xolair	
Diagnosis	IgE-Mediated Food Allergy
Approval Length	20 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of IgE Mediated Food Allergy as evidenced by one of the following:

Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food

Positive food specific IgE (greater than or equal to 6 kUA/L)

Positive oral food challenge, defined as experiencing dose-limiting symptoms at a single dose of less than or equal to 300 mg of food protein

AND

1.1.2 Clinical history of IgE Mediated Food Allergy

OR

1.2 Provider attestation that patient has a history of severe allergic response, including anaphylaxis, following exposure to one or more foods

AND

2 - Patient is 1 year of age or older

AND

3 - Used in conjunction with food allergen avoidance

AND

4 - Both of the following:

Baseline (pre-Xolair treatment) serum total IgE level is greater than or equal to 30 IU/mL and less than or equal to 1850 IU/mL

Dosing is according to serum total IgE levels and body weight

AND

5 - Prescribed by or in consultation with one of the following:

Allergist

Immunologist

Product Name:Xolair	
Diagnosis	IgE-Mediated Food Allergy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy(e.g., reduction of type 1 allergic reactions, including anaphylaxis, following accidental exposure to one or more foods)

AND

2 - Used in conjunction with food allergen avoidance

AND

3 - Dosing will continue to be based on body weight and pretreatment total IgE serum levels

AND

4 - Prescribed by or in consultation with one of the following:

Allergist

Immunologist

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [3]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		

Mometasone furoate (pMDI, standard particle, HFA)	200-400	> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [5]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Beclometasone dipropionate (pMDI, extrafine particle, HFA)	50-100	> 100-200	> 200
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Budesonide (nebules)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle*, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50		n.a.
Fluticasone propionate (DPI)	50-100	> 100-200	> 200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	> 100-200	> 200

Mometasone furoate (pMDI, standard particle, HFA)	100	200

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

National treatment guidelines recommend the combination of an inhaled glucocorticosteroid and a long-acting beta2-agonist for the treatment of moderate persistent or severe persistent asthma. [2-5]

The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. Clinical studies for allergic asthma evaluated an initial 16-week steroid stable phase in which subjects received omalizumab with a constant dose of inhaled steroids. This 16-week period may not be sufficient amount of time to show reduction in exacerbations. For allergic asthma, initial authorization duration increased from 16 weeks to 6 months. [3, 4]

Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [3].

Sensitization to a perennial allergen (e.g., mite, cat, dog) should be required. [4] Xolair is indicated for children and adults (6 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. [1]

For chronic idiopathic urticaria, response observed at 12 weeks (one 24-week trial with data reported at 12 weeks, and one 12-week trial) [1]

Per clinical consult, April 2024.

Referral to an asthma specialist for consultation or comanagement is recommended if Xolair is being considered. [2]

Other agents used for nasal polyps include intranasal corticosteroids and nasal saline.

5 . References

Xolair Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2024.

National Heart, Lung, and Blood Institute, National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health Publication No.08-5846. Bethesda, MD, 2007. Available at: https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma. Accessed January 9, 2020.

Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023.

Per clinical consult with asthma specialist, January 6, 2011.

National Institute for Health and Care Excellence (NICE). Omalizumab for treating severe persistent allergic asthma (review of technology appraisal guidance 133 and 201). London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 64 p. (Technology appraisal guidance; no. 278). Available at https://www.nice.org.uk/guidance/ta278/resources/omalizumab-for-treating-severe-persistent-allergic-asthma-pdf-82600619176645. Accessed January 9, 2020.

Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014;133(5):1270-7.

DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed March 11, 2021.

Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immunol. 2014;113(4):347-85.

Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. Int Forum Allergy Rhinol. 2016 Feb; Suppl 1:S22-209.

A, Boyce J, Ass'ad A, Burks Wesley, A et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. Journal of Allergy and Clinical Immunology. 2010; 126(6): 1079-1378.

6 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229049
Guideline Name	Xolremdi (mavorixafor)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xolremdi (mavorixafor)
WHIM syndrome Indicated in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.

2 . Criteria

Product Name:Xolremdi	
Diagnosis	WHIM syndrome
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLREMDI	MAVORIXAFOR CAP 100 MG	82502046000120	Brand

Approval Criteria

1 - Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome

AND

2 - Patient has genotype confirmed variant of CXCR4 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Patient has an absolute neutrophil count (ANC) less than 500 cells /µL [A]

AND

4 - Patient is 12 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

Immunologist

Hematologist

Geneticist

Allergist

Product Name:Xolremdi	
Diagnosis	WHIM syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLREMDI	MAVORIXAFOR CAP 100 MG	82502046000120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in ANC, reduction in infections)

3 . Endnotes

Per consult with immunologist/ allergist, severe neutropenia (less than or equal to 500 cells per µL) is used in standard practice as a cut off for ANC levels [2].

4 . References

Xolremdi Prescribing Information. X4 Pharmaceuticals, Inc. Boston, MA. June 2024.

Per clinical consult with immunologist/ allergist, June 27, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228592
Guideline Name	Xospata (gilteritinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xospata (gilteritinib) tablets
Relapsed or Refractory Acute Myeloid Leukemia Indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

2 . Criteria

Product Name:Xospata	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOSPATA	GILTERITINIB FUMARATE TABLET 40 MG (BASE EQUIVALENT)	21533020200320	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Disease is relapsed or refractory

AND

3 - Patient has a FMS-like tyrosine kinase 3 (FLT3) mutation as determined by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

Product Name:Xospata	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOSPATA	GILTERITINIB FUMARATE TABLET 40 MG (BASE EQUIVALENT)	21533020200320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Xospata prescribing information. Astellas Pharma US, Inc. Northbrook, IL. June 2022.

U.S. Food and Drug Administration: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools. Accessed December 13, 2019.

Prior Authorization Guideline

Guideline ID	GL-233402
Guideline Name	Xphozah (tenapanor) - ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	1/17/2024
P&T Revision Date:	1/15/2025

1 . Indications

Drug Name: Xphozah (tenapanor)
Hyperphosphatemia in Chronic Kidney Disease on Dialysis Indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

2 . Criteria

Product Name:Xphozah	
Approval Length	12 month(s)

Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
XPHOZAH	TENAPANOR HCL TAB 20 MG	30903260600325	Brand
XPHOZAH	TENAPANOR HCL TAB 30 MG	30903260600330	Brand

Approval Criteria

1 - Diagnosis of hyperphosphatemia in chronic kidney disease

AND

2 - Patient is on dialysis

AND

3 - Trial (minimum 30-day supply) and inadequate response, contraindication or intolerance to two of the following: [A-B, 2-3]

calcium carbonate

calcium acetate

lanthanum carbonate

sevelamer carbonate

sevelamer HCl

Auryxia

Product Name:Xphozah	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XPHOZAH	TENAPANOR HCL TAB 20 MG	30903260600325	Brand
XPHOZAH	TENAPANOR HCL TAB 30 MG	30903260600330	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of hyperphosphatemia in chronic kidney disease

AND

2 - Patient is on dialysis

AND

3 - Submission of medical records (e.g., chart notes) or paid claims confirming trial (minimum 30-day supply) and inadequate response, contraindication or intolerance to two of the following: [A-B, 2-3]

calcium carbonate

calcium acetate

lanthanum carbonate

sevelamer carbonate

sevelamer HCl

Auryxia

3 . Endnotes

Phosphate binders are categorized as calcium-containing and non-calcium-containing. All are equivalently effective in lowering phosphate. [2]

The Kidney Disease: Improving Global Outcomes (KDIGO) guidelines do not strongly prefer 1 type of phosphate binder over another for adults and have noted that the selection of an appropriate phosphate binder should be individualized and based on various clinical parameters, not phosphorus lowering alone. All phosphate binders are efficacious in reducing serum phosphate levels; one product has not been found to be superior over another and therapy should be individualized to meet the patient's unique medical needs [3]

4 . References

Xphozah [prescribing information]. Waltham, MA. Ardelyx Inc. October 2023.

UptoDate. Management of hyperphosphatemia in adults with chronic kidney disease. Available at: https://www.uptodate.com/contents/management-of-hyperphosphatemia-in-adults-with-chronic-kidney-disease?search=dialysis%20in%20chronic%20kidney%20disease&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4#H169682201. Accessed December 11, 2023.

KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6340919/. Accessed December 11, 2023.

5 . Revision History

Date	Notes
3/14/2025	quartz guideline copied to mirrow Optumrx

Prior Authorization Guideline

Guideline ID	GL-228597
Guideline Name	Xpovio (selinexor)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xpovio (selinexor)
Multiple Myeloma 1) Indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. 2) Indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. **Diffuse Large B-cell Lymphoma (DLBCL)** Indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

2 . Criteria

Product Name:Xpovio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XPOVIO 80 MG TWICE WEEKLY	SELINEXOR TAB THERAPY PACK 20 MG (80 MG TWICE WEEKLY)	2156006000B720	Brand
XPOVIO 60 MG TWICE WEEKLY	SELINEXOR TAB THERAPY PACK 20 MG (60 MG TWICE WEEKLY)	2156006000B755	Brand
XPOVIO	SELINEXOR TAB THERAPY PACK 40 MG (40 MG ONCE WEEKLY)	2156006000B760	Brand
XPOVIO	SELINEXOR TAB THERAPY PACK 40 MG (40 MG TWICE WEEKLY)	2156006000B765	Brand
XPOVIO	SELINEXOR TAB THERAPY PACK 40 MG (80 MG ONCE WEEKLY)	2156006000B770	Brand
XPOVIO	SELINEXOR TAB THERAPY PACK 50 MG (100 MG ONCE WEEKLY)	2156006000B775	Brand
XPOVIO	SELINEXOR TAB THERAPY PACK 60 MG (60 MG ONCE WEEKLY)	2156006000B780	Brand

Approval Criteria

1 - Diagnosis of one of the following:

Diffuse large B-cell lymphoma (DLBCL)

Multiple Myeloma

Product Name:Xpovio	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

XPOVIO 80 MG TWICE WEEKLY	SELINEXOR TAB THERAPY PACK 20 MG (80 MG TWICE WEEKLY)	2156006000B720	Brand
XPOVIO 60 MG TWICE WEEKLY	SELINEXOR TAB THERAPY PACK 20 MG (60 MG TWICE WEEKLY)	2156006000B755	Brand
XPOVIO	SELINEXOR TAB THERAPY PACK 40 MG (40 MG ONCE WEEKLY)	2156006000B760	Brand
XPOVIO	SELINEXOR TAB THERAPY PACK 40 MG (40 MG TWICE WEEKLY)	2156006000B765	Brand
XPOVIO	SELINEXOR TAB THERAPY PACK 40 MG (80 MG ONCE WEEKLY)	2156006000B770	Brand
XPOVIO	SELINEXOR TAB THERAPY PACK 50 MG (100 MG ONCE WEEKLY)	2156006000B775	Brand
XPOVIO	SELINEXOR TAB THERAPY PACK 60 MG (60 MG ONCE WEEKLY)	2156006000B780	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Xpovio Prescribing Information. Karyopharm Therapeutics Inc. Newton, MA. July 2022.

Prior Authorization Guideline

Guideline ID	GL-229052
Guideline Name	Xtandi (enzalutamide)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xtandi (enzalutamide)
Castration-resistant prostate cancer (CRPC) Indicated for the treatment of patients with castration-resistant prostate cancer (CRPC). **Metastatic castration-sensitive prostate cancer (mCSPC)** Indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). **Non-metastatic castration-sensitive prostate cancer (nmCSPC)** Indicated for the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR). **Off Label Uses: HRR Gene-mutated mCRPC [3]** Indicated for the treatment of adult patients with HRR gene-mutated metastatic castration-resistant prostate cancer (mCRPC) in combination with Talzenna (talazoparib).

2 . Criteria

Product Name:Xtandi	
Diagnosis	Castration-resistant prostate cancer (CRPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTANDI	ENZALUTAMIDE CAP 40 MG	21402430000120	Brand
XTANDI	ENZALUTAMIDE TAB 40 MG	21402430000320	Brand
XTANDI	ENZALUTAMIDE TAB 80 MG	21402430000340	Brand

Approval Criteria

1 - Diagnosis of castration-resistant (chemical or surgical) prostate cancer

AND

2 - If HRR gene-mutated metastatic disease, medication will be taken in combination with Talzenna (talazoparib)

Product Name:Xtandi	
Diagnosis	Metastatic castration-sensitive prostate cancer (mCSPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTANDI	ENZALUTAMIDE CAP 40 MG	21402430000120	Brand
XTANDI	ENZALUTAMIDE TAB 40 MG	21402430000320	Brand
XTANDI	ENZALUTAMIDE TAB 80 MG	21402430000340	Brand

Approval Criteria

1 - Diagnosis of metastatic, castration-sensitive prostate cancer

Product Name:Xtandi	
Diagnosis	Non-metastatic castration-sensitive prostate cancer (nmCSPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTANDI	ENZALUTAMIDE CAP 40 MG	21402430000120	Brand
XTANDI	ENZALUTAMIDE TAB 40 MG	21402430000320	Brand
XTANDI	ENZALUTAMIDE TAB 80 MG	21402430000340	Brand

Approval Criteria

1 - Diagnosis of non-metastatic, castration-sensitive prostate cancer (nmCSPC)

AND

2 - Patient has high-risk biochemical recurrence (BCR) defined by a PSA doubling time less than or equal to 9 months and one of the following:

PSA values greater than or equal to 1 ng/mL if the patient had prior prostatectomy (with or without radiotherapy)

PSA values at least 2 ng/mL above the nadir if the patient had prior radiotherapy only

Product Name:Xtandi	
Diagnosis	All indications listed above
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTANDI	ENZALUTAMIDE CAP 40 MG	21402430000120	Brand
XTANDI	ENZALUTAMIDE TAB 40 MG	21402430000320	Brand
XTANDI	ENZALUTAMIDE TAB 80 MG	21402430000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Xtandi prescribing information. Astellas Pharma Inc. Northbrook, IL. November 2023.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.3.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed March 2024.

Agarwal, Neeraj, et al. “Talazoparib plus Enzalutamide in Men with First-Line Metastatic Castration-Resistant Prostate Cancer (TALAPRO-2): A Randomised, Placebo-Controlled, Phase 3 Trial.” The Lancet, 4 June 2023, https://doi.org/10.1016/s0140-6736(23)01055-3.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228596
Guideline Name	Xuriden (uridine triacetate)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xuriden (uridine triacetate)
Hereditary orotic aciduria Indicated in adult and pediatric patients for the treatment of hereditary orotic aciduria.

2 . Criteria

Product Name:Xuriden	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XURIDEN	URIDINE TRIACETATE ORAL GRANULES PACKET 2 GM	30903875203020	Brand

Approval Criteria

1 - Diagnosis of hereditary orotic aciduria [A]

AND

2 - Prescribed by or in consultation with a medical geneticist or other specialist that treats inborn errors of metabolism [B]

Product Name:Xuriden	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XURIDEN	URIDINE TRIACETATE ORAL GRANULES PACKET 2 GM	30903875203020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy [C]

3 . Endnotes

Hereditary orotic aciduria (uridine monophosphate [UMP] synthase deficiency) or HOA is a rare congenital disorder of pyrimidine metabolism caused by a defect in UMP synthase, a bi-functional enzyme that catalyzes the final 2 steps of the de novo pyrimidine biosynthetic pathway in mammalian cells. Ten defects in pyrimidine metabolic pathways have been identified to date; all exhibit autosomal recessive inheritance, however, the ubiquitous presence of pyrimidine-derived compounds underlies the heterogeneity in

clinical expression, even within families, thus often making recognition difficult. While the true prevalence of these rare disorders is unknown, inborn errors of pyrimidine metabolism are now increasingly being recognized in adults with partial deficiencies, and so may present from birth onwards. [1-2]

Three subtypes of HOA have been described; alongside clinical presentation (notably macrocytic hypochromic megaloblastic anemia and crystalluria), the ratio of urinary orotidine to orotate provides a means of differentiating the 3 subtypes. The enzyme defect in HOA can be bypassed by the administration of oral uridine which is not Food and Drug Administration-approved, but is available over-the-counter in various dietary/food supplements or as a bulk powder from which doses may be compounded; oral uridine has been used as a treatment for patients with HOA for more than 4 decades. Because uridine is widely used for several non-HOA conditions, the addition of a specialist prescriber requirement was added to reserve the use of XURIDEN for those patients with rare HOA. [1-4]

The recommended starting dosage of oral Xuriden is 60 mg/kg once daily. The dose can be increased to 120 mg/kg (not to exceed 8 grams) once daily for insufficient efficacy, such as the occurrence of one of the following: (1) levels of orotic acid in urine remain above normal or increase above the usual or expected range for the patient, (2) laboratory values (eg, red blood cell or white blood cell indices) affected by hereditary orotic aciduria show evidence of worsening, or (3) worsening of other signs or symptoms of the disease. Case reports have demonstrated that the effects of exogenous uridine were maintained over months and years, as long as treatment continued at sufficient doses (with appropriate dose increases based on body weight increases). Most hematologic abnormalities and orotic aciduria reappeared within days to up to 2 or 3 weeks when administration of uridine was stopped or the dose was reduced. If treatment was interrupted for longer periods, body weight growth receded. [1]

4 . References

Xuriden Prescribing Information. Wellstat Therapeutics Corporation, December 2019.

Balasubramaniam S, Duley JA, Christodoulou J. Inborn errors of pyrimidine metabolism: clinical update and therapy. J Inherit Metab Dis. 2014;37(5):687-98.

Jurecka A. Inborn errors of purine and pyrimidine metabolism. J Inherit Metab Dis. 2009;32(2):247-263.

Weinberg ME, Roman MC, Jacob P, et al. Enhanced uridine bioavailability following administration of a triacetyluridine-rich nutritional supplement. PloS one. 2011;6(2).

Prior Authorization Guideline

Guideline ID	GL-229053
Guideline Name	Yonsa (abiraterone acetate) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Yonsa (abiraterone acetate)
Metastatic Castration-Resistant Prostate Cancer (mCRPC) Indicated in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer.

2 . Criteria

Product Name:Yonsa	
Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
YONSA	ABIRATERONE ACETATE MICRONIZED TAB 125 MG	21406010250310	Brand

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 For continuation of prior therapy

Product Name:Yonsa	
Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
YONSA	ABIRATERONE ACETATE MICRONIZED TAB 125 MG	21406010250310	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Yonsa

Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
YONSA	ABIRATERONE ACETATE MICRONIZED TAB 125 MG	21406010250310	Brand

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

Yonsa prescribing information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. July 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed May 3, 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Yorvipath (palopegteriparatide)

Prior Authorization Guideline

Guideline ID	GL-233308
Guideline Name	Yorvipath (palopegteriparatide)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	11/21/2024
P&T Revision Date:	

1 . Indications

Drug Name: Yorvipath (palopegteriparatide)
Hypoparathyroidism Indicated for the treatment of hypoparathyroidism in adults. Limitations of Use: (1) Not studied for acute post-surgical hypoparathyroidism; (2) Titration scheme only evaluated in adults who first achieved an albumin-corrected serum calcium of at least 7.8 mg/dL using calcium and active vitamin D treatment

2 . Criteria

Product Name:Yorvipath	
Approval Length	6 Months [A-C, 1-4]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
YORVIPATH	PALOPEGTERIPARATIDE PEN-INJ 168 MCG/0.56ML (TERIPARATIDE EQ)	3090516000D220	Brand
YORVIPATH	PALOPEGTERIPARATIDE PEN-INJ 294 MCG/0.98ML (TERIPARATIDE EQ)	3090516000D230	Brand
YORVIPATH	PALOPEGTERIPARATIDE PEN-INJ 420 MCG/1.4ML (TERIPARATIDE EQ)	3090516000D240	Brand

Approval Criteria

1 - Diagnosis of hypoparathyroidism

AND

2 - Requested drug is not being used in the setting of acute post-surgical hypoparathyroidism [1]

AND

3 - Patient has achieved albumin-corrected serum calcium of at least 7.8 mg/dL using calcium and active vitamin D (e.g., calcitriol) treatment [D-F, 1, 2, 5]

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name:Yorvipath	
Approval Length	12 Months [3,4]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
YORVIPATH	PALOPEGTERIPARATIDE PEN-INJ 168 MCG/0.56ML (TERIPARATIDE EQ)	3090516000D220	Brand
YORVIPATH	PALOPEGTERIPARATIDE PEN-INJ 294 MCG/0.98ML (TERIPARATIDE EQ)	3090516000D230	Brand
YORVIPATH	PALOPEGTERIPARATIDE PEN-INJ 420 MCG/1.4ML (TERIPARATIDE EQ)	3090516000D240	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by maintenance of normalized calcium levels compared to baseline

3 . Endnotes

Patients randomized to Yorvipath therapy in the PaTHway pivotal trial were given therapy for 26-week duration. [1, 2]

An international systematic current practice survey of expert panelists recommends monitoring patients every 6 to 12 months as the optimal strategy for stable patients with chronic hypoparathyroidism. For patients with changes in therapy, such as treatment initiation or dosage titration, monitoring should be done more frequently than the 1 to 2 times per year for well-controlled patients. [3, 4]

In the PaTHway pivotal trial, patients were monitored within 1 to 2 weeks after any dosage adjustments. [2]

Patients eligible for inclusion in the PaTHway trial must have been treated with conventional therapy for at least 12 weeks prior to screening. [2]

Serum calcium concentration should be measured within 7 to 10 days of Yorvipath initiation. Doses of active vitamin D or calcium supplement or both should be adjusted based on serum calcium value and clinical assessment (i.e., signs and symptoms of hypocalcemia or hypercalcemia). [1]

Throughout the trial, most patients treated with Yorvipath maintained serum calcium levels in normal range upon discontinuation of active vitamin D and calcium therapies. [5]

4 . References

Yorvipath Prescribing Information. Ascendis Pharma. Princeton, NJ. August 2024.

Khan AA, Rubin MR, Schwarz P, et al. Efficacy and safety of parathyroid hormone replacement with TransCon PTH in hypoparathyroidism: 26-week results from the phase 3 PaTHway trial. Journal of Bone and Mineral Research. 2023;38:14-25.

Khan AA, Bilezikian JP, Brandi ML, et al. Evaluation and management of hypoparathyroidism summary statement and guidelines from the Second International Workshop. Journal of Bone and Mineral Research. 2022;37(12):2568-85.

Brandi ML, Bilezikian JP, Shoback D, et al. Management of hypoparathyroidism: summary statement and guidelines. Journal of Clinical Endocrinology and Metabolism. 2016;101(6):2273-83.

FDA Review: Yorvipath. Food and Drug Administration Web Site. 2024. http://www.accessdata.fda.gov. Accessed September 9, 2024.

5 . Revision History

Date	Notes
1/10/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-228601
Guideline Name	Zejula (niraparib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zejula (niraparib)
First-Line Maintenance Treatment of Advanced Ovarian Cancer Indicated for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy. **Maintenance Treatment of Recurrent Germline BRCA-mutated Ovarian Cancer** Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

2 . Criteria

Product Name:Zejula

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEJULA	NIRAPARIB TOSYLATE CAP 100 MG (BASE EQUIVALENT)	21535550200120	Brand
ZEJULA	NIRAPARIB TOSYLATE TAB 100 MG (BASE EQUIVALENT)	21535550200320	Brand
ZEJULA	NIRAPARIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21535550200330	Brand
ZEJULA	NIRAPARIB TOSYLATE TAB 300 MG (BASE EQUIVALENT)	21535550200340	Brand

Approval Criteria

1 - Diagnosis of one of the following:

Epithelial ovarian cancer

Fallopian tube cancer

Primary peritoneal cancer

Product Name:Zejula	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEJULA	NIRAPARIB	21535550200120	Brand
ZEJULA	NIRAPARIB TOSYLATE CAP 100 MG (BASE EQUIVALENT)	21535550200120	Brand
ZEJULA	NIRAPARIB TOSYLATE TAB 100 MG (BASE EQUIVALENT)	21535550200320	Brand
ZEJULA	NIRAPARIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)	21535550200330	Brand

ZEJULA	NIRAPARIB TOSYLATE TAB 300 MG (BASE EQUIVALENT)	21535550200340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zejula Prescribing Information. GlaxoSmithKline, LLC. Research Triangle Park, NC. April 2023.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer v.1.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed April 21, 2022.

Zelboraf (vemurafenib)

Prior Authorization Guideline

Guideline ID	GL-229056
Guideline Name	Zelboraf (vemurafenib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zelboraf (vemurafenib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. Limitation of Use: ZELBORAF is not indicated for treatment of patients with wild-type BRAF melanoma. **Erdheim-Chester Disease** Indicated for the treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation.

2 . Criteria

Product Name:Zelboraf	
Diagnosis	Melanoma
Approval Length	12 Month [A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZELBORAF	VEMURAFENIB TAB 240 MG (BASE EQUIVALENT)	21532080000320	Brand
ZELBORAF	VEMURAFENIB TAB 240 MG	21532080000320	Brand

Approval Criteria

1 - One of the following diagnoses: [2]

Unresectable melanoma

Metastatic melanoma

AND

2 - Cancer is BRAF V600 mutant type as detected by an FDA-approved test (e.g., cobas 4600 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name:Zelboraf	
Diagnosis	Erdheim-Chester Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZELBORAF	VEMURAFENIB TAB 240 MG (BASE EQUIVALENT)	21532080000320	Brand
ZELBORAF	VEMURAFENIB TAB 240 MG	21532080000320	Brand

Approval Criteria

1 - Diagnosis of Erdheim-Chester disease (ECD)

AND

2 - Disease is BRAF V600 mutant type (MT)

Product Name:Zelboraf	
Diagnosis	All Indications
Approval Length	12 Month [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZELBORAF	VEMURAFENIB TAB 240 MG (BASE EQUIVALENT)	21532080000320	Brand
ZELBORAF	VEMURAFENIB TAB 240 MG	21532080000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

In the pivotal trial (Trial 1) evaluating treatment naive patients who received Zelboraf (vemurafenib), the median follow-up was 6.2 months and the median progression free survival (PFS) was 5.3 months (95% CI, 4.9 - 6.6). In the pivotal trial (Trial 2) evaluating Zelboraf (vemurafenib) in patients who received prior systemic therapy, the best overall response rate was 52% (95% CI, 43 - 61%), the median time to response was 1.4 months, and the median duration of response was 6.5 months (95% CI, 5.6 - not reached). [1] According to the NCCN melanoma guidelines, Zelboraf (vemurafenib) is associated with a 40-50% response rate in patients with a V600 mutated BRAF gene; however, the median duration of response is only 5 - 6 months. [2]

4 . References

Zelboraf Prescribing Information. Genentech USA, Inc., May 2020.

National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 13, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Zepatier (elbasvir/grazoprevir)

Prior Authorization Guideline

Guideline ID	GL-229058
Guideline Name	Zepatier (elbasvir/grazoprevir)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zepatier (elbasvir/grazoprevir)
Chronic Hepatitis C (CHC) Indicated with or without ribavirin for the treatment of chronic hepatitis C virus (HCV) genotypes 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg.

2 . Criteria

Product Name:Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1a: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced WITHOUT baseline NS5A polymorphisms*
Approval Length	12 Week(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPATIER	ELBASVIR-GRAZOPREVIR TAB 50-100 MG	12359902300320	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1a

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - One of the following:

3.1 Patient is treatment-naive

OR

3.2 Patient has prior failure to peginterferon alfa plus ribavirin treatment

OR

3.3 Both of the following:

Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

Used in combination with ribavirin

AND

4 - Both of the following: [1, A]

4.1 Patient has been tested for the presence of NS5A resistance-associated polymorphisms

AND

4.2 Patient is without baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)

AND

5 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

7 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Notes	*NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

Product Name:Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1a: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced WITH baseline NS5A polymorphisms*
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPATIER	ELBASVIR-GRAZOPREVIR TAB 50-100 MG	12359902300320	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1a

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - One of the following:

Patient is treatment-naive

Patient has prior failure to peginterferon alfa plus ribavirin treatment

Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

4 - Both of the following: [1, A]

4.1 Patient has been tested for the presence of NS5A resistance-associated polymorphisms

AND

4.2 Patient has baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)

AND

5 - Used in combination with ribavirin

AND

6 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

7 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

8 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

9 - One of the following:

9.1 Both of the following:

9.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

9.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

9.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Notes	*NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

Product Name:Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1b: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPATIER	ELBASVIR-GRAZOPREVIR TAB 50-100 MG	12359902300320	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1b

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - One of the following:

3.1 Patient is treatment-naive

OR

3.2 Patient has prior failure to peginterferon alfa plus ribavirin treatment

OR

3.3 Both of the following:

Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

6 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Product Name:Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 4: Treatment-naive
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPATIER	ELBASVIR-GRAZOPREVIR TAB 50-100 MG	12359902300320	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 4

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - Patient is treatment-naive

AND

4 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

6 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Product Name:Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 4: PegIFN/RBV-experienced
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPATIER	ELBASVIR-GRAZOPREVIR TAB 50-100 MG	12359902300320	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 4

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - Patient has prior failure to peginterferon alfa plus ribavirin treatment

AND

4 - Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

7 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

3 . Endnotes

Testing patients with HCV genotype 1a infection for the presence of virus with NS5A resistance-associated polymorphisms is recommended prior to initiation of treatment with Zepatier to determine dosage regimen and duration. In subjects receiving Zepatier for 12 weeks, sustained virologic response (SVR12) rates were lower in genotype 1a-infected patients with one or more baseline NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93. [1]

Zepatier is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) due to the expected significantly increased grazoprevir plasma concentration and the increased risk of alanine aminotransferase (ALT) elevations. [1]

4 . References

Zepatier Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. December 2021.

American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

5 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Zeposia (ozanimod)

Prior Authorization Guideline

Guideline ID	GL-229072
Guideline Name	Zeposia (ozanimod)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPOSIA 7-DAY STARTER PACK	OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG	6240705020B210	Brand

ZEPOSIA STARTER KIT	OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG & 21 X 0.92 MG	6240705020B215	Brand
ZEPOSIA	OZANIMOD HCL CAP 0.92 MG	62407050200120	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPOSIA 7-DAY STARTER PACK	OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG	6240705020B210	Brand
ZEPOSIA STARTER KIT	OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG & 21 X 0.92 MG	6240705020B215	Brand
ZEPOSIA	OZANIMOD HCL CAP 0.92 MG	62407050200120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPOSIA 7-DAY STARTER PACK	OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG	6240705020B210	Brand
ZEPOSIA STARTER KIT	OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG & 21 X 0.92 MG	6240705020B215	Brand
ZEPOSIA	OZANIMOD HCL CAP 0.92 MG	62407050200120	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [4, 5]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, ESR, CRP)

Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [4, 5]:

6-mercaptopurine

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

Azathioprine

Corticosteroids (e.g., prednisone)

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following:

One formulary adalimumab product*

Simponi (golimumab)

One formulary ustekinumab product*

Omvoh (mirikizumab-mrkz)

Skyrizi (risankizumab-rzaa)

Tremfya (guselkumab)

Rinvoq (upadacitinib)

Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with a gastroenterologist

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name:Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPOSIA 7-DAY STARTER PACK	OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG	6240705020B210	Brand
ZEPOSIA STARTER KIT	OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG & 21 X 0.92 MG	6240705020B215	Brand
ZEPOSIA	OZANIMOD HCL CAP 0.92 MG	62407050200120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [3-5]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

2 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products
Adalimumab-adaz
Hyrimoz
Hadlima
Adalimumab-fkjp

3 . Endnotes

According to the National MS Society, of the four disease courses that have been identified in MS, relapsing-remitting MS (RRMS) is characterized primarily by relapses, and secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. These two constitute “relapsing forms of MS” if they describe a disease course that is characterized by the occurrence of relapses. [2] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [1]

4 . References

Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.

National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed March 29, 2019.

Zeposia Prescribing Information. Celgene Corporation. Summit, NJ. June 2023.

Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.

Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

5 . Revision History

Date	Notes
12/20/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-228600
Guideline Name	Zilbrysq (zilucoplan injection)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zilbrysq (zilucoplan injection)
Generalized myasthenia gravis (gMG) Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive

2 . Criteria

Product Name:Zilbrysq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZILBRYSQ	ZILUCOPLAN SODIUM SUBCUTANEOUS SOLN PREF SYR 16.6 MG/0.416ML	8580509520E520	Brand
ZILBRYSQ	ZILUCOPLAN SODIUM SUBCUTANEOUS SOLN PREF SYR 23 MG/0.574ML	8580509520E530	Brand
ZILBRYSQ	ZILUCOPLAN SODIUM SUBCUTANEOUS SOLN PREF SYR 32.4 MG/0.81ML	8580509520E540	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following: [2, 3]

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

Chronic plasmapheresis or plasma exchange (PE)

Intravenous immunoglobulin (IVIG)

AND

4 - Both of the following:

4.1 Trial and failure, contraindication, or intolerance to one of the following:

Soliris

Ultomiris

AND

4.2 Trial and failure, contraindication, or intolerance to one of the following:

Rystiggo

Vyvgart

Vyvgart Hytrulo

AND

5 - Prescribed by or in consultation with a neurologist

Product Name:Zilbrysq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZILBRYSQ	ZILUCOPLAN SODIUM SUBCUTANEOUS SOLN PREF SYR 16.6 MG/0.416ML	8580509520E520	Brand

ZILBRYSQ	ZILUCOPLAN SODIUM SUBCUTANEOUS SOLN PREF SYR 23 MG/0.574ML	8580509520E530	Brand
ZILBRYSQ	ZILUCOPLAN SODIUM SUBCUTANEOUS SOLN PREF SYR 32.4 MG/0.81ML	8580509520E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Both of the following:

2.1 Trial and failure, contraindication, or intolerance to one of the following:

Soliris

Ultomiris

AND

2.2 Trial and failure, contraindication, or intolerance to one of the following:

Rystiggo

Vyvgart

Vyvgart Hytrulo

3 . References

Zilbrysq Prescribing Information. UCB, Inc. Smyrna, GA. October 2023.

Howard JF Jr, Utsugisawa K, Benatar M, et al. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study. Lancet Neurol. 2017 Dec;16(12):976-986.

Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.

Prior Authorization Guideline

Guideline ID	GL-229060
Guideline Name	Zokinvy (lonafarnib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zokinvy (lonafarnib)
Hutchinson-Gilford Progeria Syndrome (HGPS) Indicated in patients 12 months of age and older with a body surface area (BSA) of 0.39 m^2 and above to reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS). Limitations of Use: ZOKINVY is not indicated for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies. Based upon its mechanism of action, ZOKINVY would not be expected to be effective in these populations. **Processing-Deficient Progeroid Laminopathies** Indicated in patients 12 months of age and older with a body surface area (BSA) of 0.39 m^2 and above for the treatment of processing-deficient Progeroid Laminopathies with either heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations. Limitations of Use: ZOKINVY is not indicated for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies. Based upon its mechanism of action, ZOKINVY would not be expected to be effective in these populations.

2 . Criteria

Product Name:Zokinvy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZOKINVY	LONAFARNIB CAP 50 MG	99463045000120	Brand
ZOKINVY	LONAFARNIB CAP 75 MG	99463045000130	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Hutchinson-Gilford Progeria Syndrome

OR

1.2 For treatment of processing-deficient Progeroid Laminopathies with one of the following:

Heterozygous LMNA mutation with progerin-like protein accumulation

Homozygous or compound heterozygous ZMPSTE24 mutations

AND

2 - Patient is 12 months of age or older

AND

3 - Patient has a body surface area of 0.39 m^2 and above

3 . References

Zokinvy Prescribing Information. Eiger BioPharmaceuticals, Inc. Palo Alto, CA. November 2020.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-229062
Guideline Name	Zolinza (vorinostat)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zolinza (vorinostat)
Cutaneous T-cell Lymphoma Indicated for treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies.

2 . Criteria

Product Name:Zolinza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZOLINZA	VORINOSTAT CAP 100 MG	21531575000120	Brand

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma

AND

2 - One of the following: [2]

2.1 Patient has progressive, persistent or recurrent disease on or following two systemic therapies (e.g., extracorporeal photopheresis [ECP], systemic retinoids, interferons) [A]

OR

2.2 History of contraindication or intolerance to other systemic therapies (e.g., Adcetris [brentuximab vedotin, Cytoxan [cyclophosphamide], Poteligeo [mogamulizumab]) [A]

Product Name:Zolinza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZOLINZA	VORINOSTAT CAP 100 MG	21531575000120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

Examples of systemic therapies include (but are not limited to): [2] Adcetris (brentuximab vedotin), Cytoxan (cyclophosphamide), Doxil (pegylated doxorubicin), Extracorporeal photochemotherapy, Folotyn (pralatrexate), Gemzar (gemcitabine), Interferon-alpha, Leukeran (chlorambucil), Nipent (pentostatin), Poteligeo (mogamulizumab), Targretin (bexarotene), Temodar (temozolamide), Toposar (etoposide), Trexall (methotrexate), Velcade (bortezomib)

4 . References

Zolinza Prescribing Information. Merck & Co, Inc. Whitehouse Station, NJ. July 2022

National comprehensive cancer network (NCCN) clinical practice guidelines in oncology: Primary cutaneous lymphomas. v.2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed August 6, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228604
Guideline Name	Zoryve (roflumilast) – PA, ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zoryve (roflumilast) 0.3% cream
Plaque Psoriasis (PsO) Indicated for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.
Drug Name: Zoryve (roflumilast) 0.15% cream
Atopic Dermatitis (AD) Indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.
Drug Name: Zoryve (roflumilast) foam
Seborrheic Dermatitis Indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

2 . Criteria

Product Name:Zoryve 0.3% cream	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST CREAM 0.3%	90230061003730	Brand

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Patient is 6 years of age or older

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to ONE of the following generic topical therapies [3]:

Corticosteroids (e.g., betamethasone, clobetasol)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Combination topical therapy (e.g., vitamin D analog/corticosteroid)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Zoryve 0.3% cream	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST CREAM 0.3%	90230061003730	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by one of the following [1, 3]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Zoryve 0.3% cream	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST CREAM 0.15%	90230061003720	Brand
ZORYVE	ROFLUMILAST CREAM 0.3%	90230061003730	Brand
ZORYVE	ROFLUMILAST FOAM 0.3%	90230061003920	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of plaque psoriasis

AND

2 - Patient is 6 years of age or older

AND

3 - Both of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to THREE of the following generic topical therapies [3]:

Corticosteroids (e.g., betamethasone, clobetasol)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Combination topical therapy (e.g., vitamin D analog/corticosteroid)

AND

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Vtama (tapinarof)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Zoryve 0.15% cream	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST CREAM 0.15%	90230061003720	Brand

Approval Criteria

1 - Diagnosis of mild to moderate atopic dermatitis

AND

2 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to ALL of the following [4]:

Medium or higher potency topical corticosteroid

Pimecrolimus cream OR Tacrolimus ointment

Eucrisa (crisaborole) ointment*

Notes	*Product may require step therapy

Product Name:Zoryve 0.15% cream	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST CREAM 0.15%	90230061003720	Brand
ZORYVE	ROFLUMILAST CREAM 0.3%	90230061003730	Brand
ZORYVE	ROFLUMILAST FOAM 0.3%	90230061003920	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of mild to moderate atopic dermatitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to ALL of the following [4]:

Medium or higher potency topical corticosteroid

Pimecrolimus cream OR Tacrolimus ointment

Eucrisa (crisaborole) ointment*

Notes	*Product may require step therapy

Product Name:Zoryve foam	
Diagnosis	Seborrheic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST FOAM 0.3%	90230061003920	Brand

Approval Criteria

1 - Diagnosis of seborrheic dermatitis

AND

2 - Patient is 9 years of age or older

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to TWO of the following generic topical therapies [2, 5, 6]:

Corticosteroids (e.g., betamethasone, clobetasol)

Antifungals (e.g., ciclopirox, ketoconazole)

Calcineurin inhibitors (e.g., tacrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Zoryve foam	
Diagnosis	Seborrheic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST FOAM 0.3%	90230061003920	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for one of the following [2, 7]:

Scaling

Erythema

Pruritus

Body surface area (BSA) involvement

Product Name:Zoryve foam

Diagnosis	Seborrheic Dermatitis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST FOAM 0.3%	90230061003920	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of seborrheic dermatitis

AND

2 - Patient is 9 years of age or older

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to TWO of the following generic topical therapies [2, 5, 6]:

Corticosteroids (e.g., betamethasone, clobetasol)

Antifungals (e.g., ciclopirox, ketoconazole)

Calcineurin inhibitors (e.g., tacrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

3 . Background

Benefit/Coverage/Program Information

Table 1. Relative potencies of topical corticosteroids [4]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05

	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . References

Zoryve Cream Prescribing Information. Arcutis Biotherapeutics Inc. Westlake Village, CA. July 2024.

Zoryve Foam Prescribing Information. Arcutis Biotherapeutics Inc. Westlake Village, CA. December 2023.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.

Clark GW, Pope SM, Jaboori KA. Diagnosis and treatment of seborrheic dermatitis. Am Fam Physician. 2015; 91(3):185-90.

Sasseville, D. Seborrheic dermatitis in adolescents and adults. Available at: https://www.uptodate.com/contents/seborrheic-dermatitis-in-adolescents-and-adults?source=history_widget#H27253022. Accessed January 25, 2004.

Zirwas, MJ, Draelos ZD, DuBois J, et al. Efficacy of roflumilast foam, 0.3%, in patients with seborrheic dermatitis: a double-blind, vehicle-controlled phase 2a randomized clinical trial. JAMA Dermatol. 2023; 159(6):613-620.

Prior Authorization Guideline

Guideline ID	GL-228602
Guideline Name	Zoryve (roflumilast) – PA, ST, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zoryve (roflumilast) 0.3% cream
Plaque Psoriasis (PsO) Indicated for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.
Drug Name: Zoryve (roflumilast) 0.15% cream
Atopic Dermatitis (AD) Indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.
Drug Name: Zoryve (roflumilast) foam
Seborrheic Dermatitis Indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

2 . Criteria

Product Name:Zoryve 0.3% cream	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST CREAM 0.3%	90230061003730	Brand

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Patient is 6 years of age or older

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to ONE of the following generic topical therapies [3]:

Corticosteroids (e.g., betamethasone, clobetasol)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Combination topical therapy (e.g., vitamin D analog/corticosteroid)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Zoryve 0.3% cream	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST CREAM 0.3%	90230061003730	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by one of the following [1, 3]:

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Zoryve 0.3% cream	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST CREAM 0.15%	90230061003720	Brand
ZORYVE	ROFLUMILAST CREAM 0.3%	90230061003730	Brand
ZORYVE	ROFLUMILAST FOAM 0.3%	90230061003920	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of plaque psoriasis

AND

2 - Patient is 6 years of age or older

AND

3 - Both of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to THREE of the following generic topical therapies [3]:

Corticosteroids (e.g., betamethasone, clobetasol)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Combination topical therapy (e.g., vitamin D analog/corticosteroid)

AND

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Vtama (tapinarof)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Zoryve 0.15% cream	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST CREAM 0.15%	90230061003720	Brand

Approval Criteria

1 - Diagnosis of mild to moderate atopic dermatitis

AND

2 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to ALL of the following [4]:

Medium or higher potency topical corticosteroid

Pimecrolimus cream OR Tacrolimus ointment

Eucrisa (crisaborole) ointment*

Notes	*Product may require step therapy

Product Name:Zoryve 0.15% cream	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST CREAM 0.15%	90230061003720	Brand
ZORYVE	ROFLUMILAST CREAM 0.3%	90230061003730	Brand
ZORYVE	ROFLUMILAST FOAM 0.3%	90230061003920	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of mild to moderate atopic dermatitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to ALL of the following [4]:

Medium or higher potency topical corticosteroid

Pimecrolimus cream OR Tacrolimus ointment

Eucrisa (crisaborole) ointment*

Notes	*Product may require step therapy

Product Name:Zoryve foam	
Diagnosis	Seborrheic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST FOAM 0.3%	90230061003920	Brand

Approval Criteria

1 - Diagnosis of seborrheic dermatitis

AND

2 - Patient is 9 years of age or older

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to TWO of the following generic topical therapies [2, 5, 6]:

Corticosteroids (e.g., betamethasone, clobetasol)

Antifungals (e.g., ciclopirox, ketoconazole)

Calcineurin inhibitors (e.g., tacrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Zoryve foam	
Diagnosis	Seborrheic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST FOAM 0.3%	90230061003920	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for one of the following [2, 7]:

Scaling

Erythema

Pruritus

Body surface area (BSA) involvement

Product Name:Zoryve foam

Diagnosis	Seborrheic Dermatitis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZORYVE	ROFLUMILAST FOAM 0.3%	90230061003920	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of seborrheic dermatitis

AND

2 - Patient is 9 years of age or older

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to TWO of the following generic topical therapies [2, 5, 6]:

Corticosteroids (e.g., betamethasone, clobetasol)

Antifungals (e.g., ciclopirox, ketoconazole)

Calcineurin inhibitors (e.g., tacrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

3 . Background

Benefit/Coverage/Program Information

Table 1. Relative potencies of topical corticosteroids [4]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05

	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . References

Zoryve Cream Prescribing Information. Arcutis Biotherapeutics Inc. Westlake Village, CA. July 2024.

Zoryve Foam Prescribing Information. Arcutis Biotherapeutics Inc. Westlake Village, CA. December 2023.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.

Clark GW, Pope SM, Jaboori KA. Diagnosis and treatment of seborrheic dermatitis. Am Fam Physician. 2015; 91(3):185-90.

Sasseville, D. Seborrheic dermatitis in adolescents and adults. Available at: https://www.uptodate.com/contents/seborrheic-dermatitis-in-adolescents-and-adults?source=history_widget#H27253022. Accessed January 25, 2004.

Zirwas, MJ, Draelos ZD, DuBois J, et al. Efficacy of roflumilast foam, 0.3%, in patients with seborrheic dermatitis: a double-blind, vehicle-controlled phase 2a randomized clinical trial. JAMA Dermatol. 2023; 159(6):613-620.

Prior Authorization Guideline

Guideline ID	GL-228754
Guideline Name	Ztalmy (ganaxolone)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ztalmy (ganaxolone)
Seizures Indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.

2 . Criteria

Product Name:Ztalmy	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZTALMY	GANAXOLONE SUSP 50 MG/ML	72600033001820	Brand

Approval Criteria

1 - Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)

AND

2 - Patient has a mutation in the CDKL5 gene

AND

3 - Patient is 2 years of age or older

AND

4 - Patient is experiencing motor seizures (e.g., bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, focal, or bilateral tonic-clonic)

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to two formulary anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine)

OR

5.2 For continuation of prior therapy

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Ztalmy	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZTALMY	GANAXOLONE SUSP 50 MG/ML	72600033001820	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by a reduction in the frequency of seizures from baseline

3 . References

Ztalmy Prescribing Information. Marinus Pharmaceuticals, Inc. Radnor, PA. April 2024.

Zulresso (brexanolone)

Prior Authorization Guideline

Guideline ID	GL-228759
Guideline Name	Zulresso (brexanolone)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zulresso (brexanolone)
Postpartum Depression (PPD) Indicated for the treatment of PPD in patients 15 years of age or older.

2 . Criteria

Product Name:Zulresso	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

ZULRESSO	BREXANOLONE IV SOLN 100 MG/20ML (5 MG/ML)	58060015002020	Brand

Approval Criteria

1 - Diagnosis of postpartum depression (PPD)

AND

2 - Patient is 15 years of age or older

AND

3 - Onset of symptoms during the third trimester of pregnancy or within 4 weeks of delivery [1, 2]

AND

4 - Patient is 6 months postpartum or less [2]

3 . References

Zulresso Prescribing Information. Sage Therapeutics, Inc. Cambridge, MA. June 2022.

Psychopharmacologic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee Meeting. FDA Briefing Document. November 2, 2018. Available at: https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM624643.pdf. Accessed March 27, 2024.

Zurzuvae (zuranolone)

Prior Authorization Guideline

Guideline ID	GL-228756
Guideline Name	Zurzuvae (zuranolone)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zurzuvae (zuranolone)
Postpartum Depression (PPD) Indicated for the treatment of PPD in women 18 years of age and older

2 . Criteria

Product Name:Zurzuvae			
Approval Length	14 Day(s)		
Guideline Type	Prior Authorization		
Product Name	Generic Name	GPI	Brand/Generic

ZURZUVAE	ZURANOLONE CAP 20 MG	58060090000120	Brand
ZURZUVAE	ZURANOLONE CAP 25 MG	58060090000125	Brand
ZURZUVAE	ZURANOLONE CAP 30 MG	58060090000130	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of moderate to severe postpartum depression (PPD)

OR

1.2 Both of the following:

1.2.1 Diagnosis of mild postpartum depression (PPD)

AND

1.2.2 Trial and failure, contraindication or intolerance to at least one oral SSRI or SNRI (e.g., escitalopram, duloxetine)

AND

2 - Patient is 18 years of age or older

AND

3 - Onset of symptoms in the third trimester or within 4 weeks of delivery

AND

4 - Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 12 hours after taking each dose of Zurzuvae for the duration of the 14-day treatment course and that

patients are informed that they may not be able to assess their own driving competence or the degree of driving impairment caused by Zurzuvae

3 . References

Zurzuvae Prescribing Information. Biogen MA Inc. November 2023.

Prior Authorization Guideline

Guideline ID	GL-233223
Guideline Name	Zyclara (imiquimod)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	9/18/2019
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Zyclara (imiquimod)
Actinic Keratosis Indicated for the topical treatment of clinically typical visible or palpable, actinic keratoses (AK) of the full face or balding scalp in immunocompetent adults. **External Genital Warts** Indicated for the treatment of external genital and perianal warts (EGW)/condyloma acuminata in patients 12 years or older.

2 . Criteria

Product Name:Zyclara 2.5% cream, Brand Zyclara 3.75% cream, Generic imiquimod 3.75% cream

Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ZYCLARA PUMP	IMIQUIMOD CREAM 2.5%	90773040003710	Brand
IMIQUIMOD PUMP	IMIQUIMOD CREAM 3.75%	90773040003715	Generic
ZYCLARA PUMP	IMIQUIMOD CREAM 3.75%	90773040003715	Generic
ZYCLARA	IMIQUIMOD CREAM 3.75%	90773040003715	Generic
IMIQUIMOD	IMIQUIMOD CREAM 3.75%	90773040003715	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), or intolerance of generic imiquimod 5%

3 . References

Zyclara prescribing information. Bausch Health US, LLC. Bridgewater, NJ. June 2020.

Eisen DB, Asgari MM, Bennett DD, et al. Guidelines of care for the management of actinic keratosis. J Am Acad Dermatol. 2021;85(4):e209-e233. doi:10.1016/j.jaad.2021.02.082.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Zydelig (idelalisib)

Prior Authorization Guideline

Guideline ID	GL-229150
Guideline Name	Zydelig (idelalisib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/10/2025
P&T Approval Date:	10/14/2014
P&T Revision Date:	10/16/2024

1 . Indications

Drug Name: Zydelig (idelalisib)
Relapsed Chronic Lymphocytic Leukemia Indicated, in combination with rituximab, for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL) for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. Limitation of Use: Zydelig is not indicated and is not recommended for first-line treatment of any patient, including patients with CLL, small lymphocytic lymphoma (SLL), follicular lymphoma (FL), and other indolent non-Hodgkin lymphomas. Zydelig is not indicated and is not recommended in combination with bendamustine and rituximab, or in combination with rituximab for the treatment of patients with FL, SLL, and other indolent non-Hodgkin lymphomas.

2 . Criteria

Product Name:Zydelig	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYDELIG	IDELALISIB TAB 100 MG	21538040000320	Brand
ZYDELIG	IDELALISIB TAB 150 MG	21538040000330	Brand

Approval Criteria

1 - Diagnosis of Chronic Lymphocytic Leukemia (CLL)

AND

2 - Patient has relapsed on at least one prior therapy (e.g., purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab])

AND

3 - Used in combination with Rituxan (rituximab)* [2]

AND

4 - Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (e.g., coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD], etc.)

Notes	*This drug may require prior authorization.

Product Name:Zydelig	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYDELIG	IDELALISIB TAB 100 MG	21538040000320	Brand
ZYDELIG	IDELALISIB TAB 150 MG	21538040000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zydelig Prescribing Information. Gilead Sciences, Inc. Foster City, CA. February 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma. v.3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed August 2, 2022.

4 . Revision History

Date	Notes
1/9/2025	Custom guideline for Quartz COM/EHB to mirrow ORx with no chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-229064
Guideline Name	Zykadia (ceritinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zykadia (ceritinib)
Non-small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

2 . Criteria

Product Name:Zykadia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYKADIA	CERITINIB TAB 150 MG	21530514000330	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - One of the following: [2]

Disease is metastatic

Disease is recurrent

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - One of the following:

4.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

Alecensa (alectinib)

Alunbrig (brigatinib)

OR

4.2 For continuation of prior therapy

Product Name:Zykadia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYKADIA	CERITINIB TAB 150 MG	21530514000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zykadia Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2022.

The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 10, 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-228605
Guideline Name	Zynlonta (loncastuximab tesirine-lpyl)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zynlonta (loncastuximab tesirine-lpyl)
Large B-cell lymphoma Indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name:Zynlonta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYNLONTA	LONCASTUXIMAB TESIRINE-LPYL FOR IV SOLN 10 MG	21351640502120	Brand

Approval Criteria

1 - One of the following diagnoses:

Diffuse large B-cell lymphoma (DLBCL)

DLBCL arising from low-grade lymphoma

High-grade B-cell lymphoma

AND

2 - Disease is one of the following:

Relapsed

Refractory

AND

3 - Patient has received at least two prior systemic therapies (e.g. chemotherapy, immunotherapy) [2]

Product Name:Zynlonta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYNLONTA	LONCASTUXIMAB TESIRINE-LPYL FOR IV SOLN 10 MG	21351640502120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zynlonta Prescribing Information. ADC Therapeutics America. Murray Hill, NJ. October 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: B-Cell Lymphomas. v.2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 23, 2024

Prior Authorization Guideline

Guideline ID	GL-228606
Guideline Name	Zynyz (retifanlimab-dlwr)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zynyz (retifanlimab-dlwr)
Merkel Cell Carcinoma (MCC) Indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2 . Criteria

Product Name:Zynyz	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYNYZ	RETIFANLIMAB-DLWR IV SOLN 500 MG/20ML (25 MG/ML)	21357960202020	Brand

Approval Criteria

1 - Diagnosis of Merkel cell carcinoma (MCC)

AND

2 - Disease is one of the following:

metastatic

recurrent locally advanced

AND

3 - Treatment duration of therapy has not exceeded a total of 24 months [A]

Product Name:Zynyz	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYNYZ	RETIFANLIMAB-DLWR IV SOLN 500 MG/20ML (25 MG/ML)	21357960202020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Treatment duration of therapy has not exceeded a total of 24 months [A]

3 . Endnotes

Zynyz is recommended to be administered until disease progression, unacceptable toxicity, or up to 24 months. There is no evidence of additional benefit beyond 24 months and a higher risk of adverse events. [1,2]

4 . References

Zynyz Prescribing Information. Incyte Corporation. Wilmington, DE. April 2024.

Per clinical consult with oncologist, May 9, 2023.

Prior Authorization Guideline

Guideline ID	GL-229066
Guideline Name	Zytiga (abiraterone acetate) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zytiga (abiraterone acetate)
Metastatic castration-resistant prostate cancer (mCRPC) Indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) in combination with prednisone. **Metastatic castration-sensitive prostate cancer (mCSPC)** Indicated for the treatment of patients with metastatic high risk castration-sensitive prostate cancer (mCSPC) in combination with prednisone.

2 . Criteria

Product Name:Brand Zytiga	
Diagnosis	Castration-resistant prostate cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYTIGA	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Brand
ZYTIGA	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Brand

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 For continuation of prior therapy

Product Name:Brand Zytiga	
Diagnosis	Castration-resistant prostate cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZYTIGA	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Brand
ZYTIGA	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Brand

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Generic abiraterone acetate	
Diagnosis	Castration-resistant prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Generic
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Generic

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

Product Name:Brand Zytiga	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYTIGA	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Brand
ZYTIGA	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Brand

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to one of the following:

Xtandi (enzalutamide)

Erleada (apalutamide)

OR

2.2 For continuation of prior therapy

Product Name:Brand Zytiga	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZYTIGA	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Brand
ZYTIGA	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Brand

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following:

Xtandi (enzalutamide)

Erleada (apalutamide)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name:Generic abiraterone acetate	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Generic
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Generic

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

Product Name:Brand Zytiga, Generic abiraterone acetate	
Diagnosis	Castration-sensitive prostate cancer, castration-resistant prostate cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYTIGA	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Brand
ZYTIGA	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Brand
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Generic
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zytiga Prescribing Information. Janssen Biotech Inc. Horsham, PA. August 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer. v.4.2018. Available by subscription at: http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf. Accessed September 18, 2018.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24