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Prescription Benefit Medication Prior Authorization Criteria for Small Group Commercial and Individual/Family

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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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July 1, 2025
Pharmacy Benefit Drug
Prior Authorization Criteria for Small Group Commercial and Individual/Family

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.

Table of Contents

Prior Authorization Guideline

Guideline ID	GL-276206
Guideline Name	Actimmune (interferon gamma-1b)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	3/21/2016
P&T Revision Date:	4/16/2025

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
5/27/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-211197
Guideline Name	Adakveo (crizanlizumab-tmca)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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-163139
Guideline Name	Adalimumab*
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

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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.

Prior Authorization Guideline

Guideline ID	GL-163406
Guideline Name	Administrative Non-Formulary & Excluded Drug Exceptions Process
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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-286219
Guideline Name	Administrative Non-Formulary Biosimilars
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025

1 . Criteria

Product Name:Abrilada, Adalimumab-AACF, Adalimumab-AATY, Adalimumab-ADBM, Adalimumab-RYVK, Amjevita, Cyltezo, Hulio, Hyrimoz (Cordavis NDCs), Idacio, Simlandi, Yuflyma, Yusimry, Pyzchiva, Selarsdi, Stelara, Ustekinumab- AEKN, Ustekinumab-TTWE, Ustekinumab, Wezlana, Humira	
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HUMIRA PEN	ADALIMUMAB AUTO-INJECTOR KIT 40 MG/0.8ML	6627001500F520	Brand
HUMIRA PEN	ADALIMUMAB AUTO-INJECTOR KIT 40 MG/0.4ML	6627001500F530	Brand

HUMIRA PEN	ADALIMUMAB AUTO-INJECTOR KIT 80 MG/0.8ML	6627001500F540	Brand
HUMIRA PEN-CD/UC/HS STARTER	ADALIMUMAB AUTO-INJECTOR KIT 80 MG/0.8ML	6627001500F540	Brand
HUMIRA PEN-PS/UV STARTER	ADALIMUMAB AUTO-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML	6627001500F550	Brand
HUMIRA	ADALIMUMAB PREFILLED SYRINGE KIT 10 MG/0.1ML	6627001500F804	Brand
HUMIRA	ADALIMUMAB PREFILLED SYRINGE KIT 20 MG/0.2ML	6627001500F809	Brand
HUMIRA	ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001500F820	Brand
HUMIRA	ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.4ML	6627001500F830	Brand
ABRILADA	ADALIMUMAB-AFZB PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001507F810	Brand
ABRILADA	ADALIMUMAB-AFZB PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001507F820	Brand
ADALIMUMAB-AACF (2 PEN)	ADALIMUMAB-AACF AUTO-INJECTOR KIT 40 MG/0.8ML	6627001502F540	Brand
ADALIMUMAB-AACF STARTER PACK/CD/UC/HS (6 PEN)	ADALIMUMAB-AACF AUTO-INJECTOR KIT 40 MG/0.8ML	6627001502F540	Brand
ADALIMUMAB-AACF STARTER PACK/PSORIASIS/UVEITIS (4 PEN)	ADALIMUMAB-AACF AUTO-INJECTOR KIT 40 MG/0.8ML	6627001502F540	Brand
ADALIMUMAB-AACF (2 SYRINGE)	ADALIMUMAB-AACF PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001502F840	Brand
YUFLYMA 1-PEN KIT	ADALIMUMAB-AATY AUTO-INJECTOR KIT 40 MG/0.4ML	6627001503F530	Brand
ADALIMUMAB-AATY 1-PEN KIT	ADALIMUMAB-AATY AUTO-INJECTOR KIT 40 MG/0.4ML	6627001503F530	Brand
YUFLYMA 2-PEN KIT	ADALIMUMAB-AATY AUTO-INJECTOR KIT 40 MG/0.4ML	6627001503F530	Brand
ADALIMUMAB-AATY 2-PEN KIT	ADALIMUMAB-AATY AUTO-INJECTOR KIT 40 MG/0.4ML	6627001503F530	Brand
ADALIMUMAB-AATY CD/UC/HS STARTER	ADALIMUMAB-AATY AUTO-INJECTOR KIT 80 MG/0.8ML	6627001503F560	Brand
YUFLYMA 1-PEN KIT	ADALIMUMAB-AATY AUTO-INJECTOR KIT 80 MG/0.8ML	6627001503F560	Brand
ADALIMUMAB-AATY 1-PEN KIT	ADALIMUMAB-AATY AUTO-INJECTOR KIT 80 MG/0.8ML	6627001503F560	Brand
YUFLYMA CD/UC/HS STARTER	ADALIMUMAB-AATY AUTO-INJECTOR KIT 80 MG/0.8ML	6627001503F560	Brand

YUFLYMA 2-SYRINGE KIT	ADALIMUMAB-AATY PREFILLED SYRINGE KIT 20 MG/0.2ML	6627001503F820	Brand
ADALIMUMAB-AATY 2-SYRINGE KIT	ADALIMUMAB-AATY PREFILLED SYRINGE KIT 20 MG/0.2ML	6627001503F820	Brand
YUFLYMA 2-SYRINGE KIT	ADALIMUMAB-AATY PREFILLED SYRINGE KIT 40 MG/0.4ML	6627001503F830	Brand
ADALIMUMAB-AATY 2-SYRINGE KIT	ADALIMUMAB-AATY PREFILLED SYRINGE KIT 40 MG/0.4ML	6627001503F830	Brand
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 80 MG/0.8ML	6627001504D540	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001504D540	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 PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML	6627001504E508	Brand
HYRIMOZ	ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001504E513	Brand
ADALIMUMAB-ADAZ	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
ADALIMUMAB-ADBM STARTER PACKAGE FOR CROHNS DISEASE/UC/HS	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.4ML	6627001505F515	Brand
CYLTEZO STARTER PACKAGE FOR CROHNS DISEASE/UC/HS	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.4ML	6627001505F515	Brand
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.4ML	6627001505F515	Brand
CYLTEZO	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.4ML	6627001505F515	Brand
CYLTEZO STARTER PACKAGE FOR PSORIASIS/UVEITIS	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.4ML	6627001505F515	Brand

ADALIMUMAB-ADBM STARTER PACKAGE FOR PSORIASIS/UVEITIS	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.4ML	6627001505F515	Brand
ADALIMUMAB-ADBM CROHNS/UC/HS STARTER	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.8ML	6627001505F520	Brand
ADALIMUMAB-ADBM PSORIASIS/UVEITIS STARTER	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.8ML	6627001505F520	Brand
CYLTEZO STARTER PACKAGE FOR CROHNS DISEASE/UC/HS	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.8ML	6627001505F520	Brand
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.8ML	6627001505F520	Brand
CYLTEZO	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.8ML	6627001505F520	Brand
CYLTEZO STARTER PACKAGE FOR PSORIASIS	ADALIMUMAB-ADBM AUTO-INJECTOR KIT 40 MG/0.8ML	6627001505F520	Brand
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM PREFILLED SYRINGE KIT 10 MG/0.2ML	6627001505F805	Brand
CYLTEZO	ADALIMUMAB-ADBM PREFILLED SYRINGE KIT 10 MG/0.2ML	6627001505F805	Brand
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001505F810	Brand
CYLTEZO	ADALIMUMAB-ADBM PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001505F810	Brand
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM PREFILLED SYRINGE KIT 40 MG/0.4ML	6627001505F815	Brand
CYLTEZO	ADALIMUMAB-ADBM PREFILLED SYRINGE KIT 40 MG/0.4ML	6627001505F815	Brand
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001505F820	Brand
CYLTEZO	ADALIMUMAB-ADBM PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001505F820	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
HULIO	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
HULIO	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand
HULIO	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

SIMLANDI 2-PEN KIT	ADALIMUMAB-RYVK AUTO-INJECTOR KIT 40 MG/0.4ML	6627001540F520	Brand
SIMLANDI 1-PEN KIT	ADALIMUMAB-RYVK AUTO-INJECTOR KIT 40 MG/0.4ML	6627001540F520	Brand
ADALIMUMAB-RYVK (2 PEN)	ADALIMUMAB-RYVK AUTO-INJECTOR KIT 40 MG/0.4ML	6627001540F520	Brand
ADALIMUMAB-RYVK	ADALIMUMAB-RYVK PREFILLED SYRINGE KIT 40 MG/0.4ML	6627001540F820	Brand
PYZCHIVA	USTEKINUMAB-TTWE IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INF)	52504070752020	Brand
USTEKINUMAB-TTWE	USTEKINUMAB-TTWE IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INF)	52504070752020	Brand
PYZCHIVA	USTEKINUMAB-TTWE SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058575E520	Brand
USTEKINUMAB-TTWE	USTEKINUMAB-TTWE SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058575E520	Brand
PYZCHIVA	USTEKINUMAB-TTWE SOLN PREFILLED SYRINGE 90 MG/ML	9025058575E540	Brand
USTEKINUMAB-TTWE	USTEKINUMAB-TTWE SOLN PREFILLED SYRINGE 90 MG/ML	9025058575E540	Brand
STELARA	USTEKINUMAB IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INFUSION)	52504070002020	Brand
USTEKINUMAB	USTEKINUMAB IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INFUSION)	52504070002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
USTEKINUMAB	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand
USTEKINUMAB	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
USTEKINUMAB	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
SELARSDI	USTEKINUMAB-AEKN IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INF)	52504070022020	Brand
SELARSDI	USTEKINUMAB-AEKN SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058502E520	Brand
USTEKINUMAB-AEKN	USTEKINUMAB-AEKN SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058502E520	Brand
SELARSDI	USTEKINUMAB-AEKN SOLN PREFILLED SYRINGE 90 MG/ML	9025058502E540	Brand
USTEKINUMAB-AEKN	USTEKINUMAB-AEKN SOLN PREFILLED SYRINGE 90 MG/ML	9025058502E540	Brand

WEZLANA	USTEKINUMAB-AUUB IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INF)	52504070032020	Brand
WEZLANA	USTEKINUMAB-AUUB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058503E520	Brand
WEZLANA	USTEKINUMAB-AUUB SOLN PREFILLED SYRINGE 90 MG/ML	9025058503E540	Brand
WEZLANA	USTEKINUMAB-AUUB INJ 45 MG/0.5ML	90250585032020	Brand
YUSIMRY	ADALIMUMAB-AQVH SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001509D520	Brand
SIMLANDI 1-PEN KIT	ADALIMUMAB-RYVK AUTO-INJECTOR KIT 80 MG/0.8ML	6627001540F540	Brand
SIMLANDI	ADALIMUMAB-RYVK PREFILLED SYRINGE KIT 20 MG/0.2ML	6627001540F810	Brand
SIMLANDI	ADALIMUMAB-RYVK PREFILLED SYRINGE KIT 40 MG/0.4ML	6627001540F820	Brand
SIMLANDI	ADALIMUMAB-RYVK PREFILLED SYRINGE KIT 80 MG/0.8ML	6627001540F840	Brand
AMJEVITA	ADALIMUMAB-ATTO SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001510D517	Brand
AMJEVITA	ADALIMUMAB-ATTO SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001510D520	Brand
AMJEVITA	ADALIMUMAB-ATTO SOLN AUTO-INJECTOR 80 MG/0.8ML	6627001510D537	Brand
AMJEVITA	ADALIMUMAB-ATTO SOLN PREFILLED SYRINGE 10 MG/0.2ML	6627001510E505	Brand
AMJEVITA	ADALIMUMAB-ATTO SOLN PREFILLED SYRINGE 20 MG/0.2ML	6627001510E508	Brand
AMJEVITA	ADALIMUMAB-ATTO SOLN PREFILLED SYRINGE 20 MG/0.4ML	6627001510E510	Brand
AMJEVITA	ADALIMUMAB-ATTO SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001510E517	Brand
AMJEVITA	ADALIMUMAB-ATTO SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001510E520	Brand

Approval Criteria

1 - Both of the following:

1.1 Submission of medical records (e.g., chart notes) documenting the patient has experienced intolerance (e.g., allergy to excipient) with all biosimilar formulary alternatives

AND

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. **AND** **2** - One of the following: **2.1** Both of the following: **2.1.1** Requested drug is FDA-approved for the condition being treated **AND** **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** **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 ex clusions should be reviewed for medical necessity. *If the target drug is listed on the ORx Commercial grid, the patient m ust 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 equivalen t product. If the diagnosis provided for the target drug is FDA approve d/compendia supported, then consider the OTC equivalent(s) to have the same FDA approval/compendia support.

2 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products Adalimumab-adaz Hyrimoz Hadlima Adalimumab-fkjp   **Formulary Ustekinumab Products:** Yesintek Steqeyma Otulfi

3 . Revision History

Date	Notes
6/15/2025	New Program

Afrezza (insulin human, inhalation powder)

Prior Authorization Guideline

Guideline ID	GL-244304
Guideline Name	Afrezza (insulin human, inhalation powder)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	8/20/2014
P&T Revision Date:	2/20/2025

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

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
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163408
Guideline Name	Akeega (niraparib and abiraterone) - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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.

Prior Authorization Guideline

Guideline ID	GL-244305
Guideline Name	Alpha-1 Proteinase Inhibitors
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/25/2016
P&T Revision Date:	3/19/2025

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
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
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. Takeda Pharmaceuticals USA Inc. Cambridge, MA October 2024.
2. Zemaira Prescribing Information. CSL Behring LLC. Kankakee, IL. January 2024.
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 (2024Report). Global Initiative for Chronic Obstructive Lung Disease. Accessed February 18, 2025.
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
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-244306
Guideline Name	Anti-Parkinson’s Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	5/22/1998
P&T Revision Date:	3/19/2025

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.
5. Gocovri Prescribing Information. Adamas Pharma, LLC. Emeryville, CA. January 2021.
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.
7. Pahwa R, Tanner CM, Hauser Ra, et al. Amantadine Extended Release for Levodopa-Induced Dyskinesia in Parkinson’s Disease (EASED Study). Mov Disorder. 2015 May; 30(6):788-95.
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
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-164958
Guideline Name	Anticonvulsants
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/10/2025
P&T Approval Date:	
P&T Revision Date:	3/20/2024

1 . Indications

Drug Name: Briviact (brivaracetam)
Partial-Onset Seizures Indicated for the treatment of partial-onset seizures in patients 1 month of age and older.

2 . Criteria

Product Name:Briviact tablet, oral solution	
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

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

3 . References

1. Briviact Prescribing Information. UCB, Inc. Smyrna, GA. September 2021.

4 . Revision History

Date	Notes
2/10/2025	Quartz EHB copied to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-244204
Guideline Name	Antidepressants
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	
P&T Revision Date:	3/19/2025

1 . Indications

Drug Name: Trintellix (vortioxetine)
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) in adults. Limitation of Use: Fetzima is not approved for the management of fibromyalgia. The efficacy and safety of Fetzima for the management of fibromyalgia have not been established.

2 . Criteria

Product Name:Trintellix	
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	Brand
TRINTELLIX	VORTIOXETINE HBR TAB 10 MG (BASE EQUIV)	58120093100320	Brand
TRINTELLIX	VORTIOXETINE HBR TAB 20 MG (BASE EQUIV)	58120093100340	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
- desvenlafaxine extended-release (ER)
- duloxetine
- escitalopram
- fluoxetine
- mirtazapine
- paroxetine or paroxetine ER
- sertraline
- venlafaxine or venlafaxine ER

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 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 extended-release (ER)
- duloxetine
- venlafaxine or venlafaxine ER

OR

2 - For continuation of prior therapy

3 . References

1. Trintellix Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. August 2023.
2. Fetzima Prescribing Information. Allergan USA, Inc. Madison, NJ. April 2024.
3. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder, third edition. Oct. 2010. http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf . Accessed January 21, 2022.
4. Soleimani L, Lapidus KA, Losifescu DV. Diagnosis and treatment of major depressive disorder. Neurol Clin. 2011;29(1):177-93.
5. American Geriatrics Society. American Geriatrics Society 2015 updated Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2015;63:2227-46.

4 . Revision History

Date	Notes
4/24/2025	Quartz guideline copied to mirrow Optum EHB.

Prior Authorization Guideline

Guideline ID	GL-163410
Guideline Name	Antiemetics Quantity Limit Overrides
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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.
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3. Emend prescribing information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. May 2022.
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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.
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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-165005
Guideline Name	Antigout Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/11/2025
P&T Approval Date:	9/28/2016
P&T Revision Date:	7/17/2024

1 . Indications

Drug Name: Uloric (febuxostat)
Gout A xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult 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.

2 . Criteria

Product Name:generic febuxostat

Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
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 allopurinol

3 . References

1. Uloric Prescribing Information. Takeda Pharmaceuticals America, Inc. Deerfield, IL. April 2023.

4 . Revision History

Date	Notes
2/11/2025	Quartz EHB copied to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-244205
Guideline Name	Apokyn
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	10/2/2004
P&T Revision Date:	3/19/2025

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:Generic apomorphine hydrochloride inj	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
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 - Not used with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Generic apomorphine hydrochloride inj	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
APOMORPHINE HYDROCHLORIDE	APOMORPHINE HCL SOLN CARTRIDGE 30 MG/3ML	7320301010E220	Generic

Approval Criteria

1 - Documentation of 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.

4 . Revision History

Date	Notes
4/24/2025	Quartz guideline copied to mirrow Optum EHB.

Prior Authorization Guideline

Guideline ID	GL-244307
Guideline Name	Atypical Antipsychotics - PA, ST
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	3/22/1998
P&T Revision Date:	3/19/2025

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: 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: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. Opipza prescribing information. Xiamen LP Pharmaceutical Co., Ltd. Fujian, China. July 2024.
9. Abilify prescribing information. Otsuka America Pharmaceutical, Inc. Rockville, MD. November 2022.
10. Saphris prescribing information. Schering Corporation. Kenilworth, NJ. July 2009.
11. Geodon prescribing information. Pfizer Inc. New York, NY. January 2022.
12. Risperdal prescribing information. Janssen Pharmaceuticals, Inc. Titusville, NJ. March 2022.
13. Seroquel XR prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. January 2022.
14. Seroquel prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. January 2022.
15. Zyprexa prescribing information. Lilly USA, LLC. Indianapolis, IN. October 2019
16. Clozaril prescribing information. HLS Therapeutics (USA), Inc. Rosemont, PA. September 2024.
17. Invega prescribing information. Janssen Pharmaceuticals, Inc. Titusville, NJ. December 2021.

4 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-244308
Guideline Name	Azole Antifungals - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	10/20/1998
P&T Revision Date:	2/20/2025

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. December 2024.
2. Sporanox Oral Solution Prescribing Information. Janssen Pharmaceuticals, Inc.; Titusville, NJ. December 2024.
3. Ely J, Rosenfeld S, Stone M. Diagnosis and Management of Tinea Infections. Aafp.org. https://www.aafp.org/afp/2014/1115/p702.html. Published 2014. Accessed October 28, 2019
4. Gupta A, Mays R. The Impact of Onychomycosis on Quality of Life: A Systematic Review of the Available Literature. Skin Appendage Disord. 2018;4(4):208-216. doi:10.1159/000485632
5. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guideline for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis. 2016;62:e1-50.
6. Stevens DA, Kan VL, Judson MA, et al. Practice Guidelines for Diseases Caused by Aspergillus. Clin Infect Dis. 2000;30:696-709.
7. McEvoy GK. AHFS Drug Information 2005. Bethesda, MD: American Society of Health-System Pharmacists, Inc; 2005.
8. 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.

9. Roberts DT, Taylor WD, Boyle J. Guidelines for treatment of onychomycosis. Br J Dermatol. 2003;148:402-410.
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.
11. Wheat LJ, Freifeld AG, Kleiman MB, et al. Clinical practice guidelines for the management of patients with histoplasmosis: 2007 update by the Infectious Diseases Society of America. Clin Infect Dis. 2007;45:807-825.
12. Patterson TF, Thompson GR, Denning DW, et al. Practice guidelines for the diagnosis and management of Aspergillosis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis. 2016;63(4):e1-60.
13. Tolsura Prescribing Information. Mayne Pharma; Greenville, NC. October 2024.
14. Noxafil Prescribing Information. Merck Sharp & Dohme Corp.; Whitehouse Station, NJ. October 2024.
15. Per Clinical Consultation with an Infectious Disease Specialist. January 24, 2014.
16. Voriconazole Tablet Prescribing Information. Ajanta Pharma Limited.; Bridgewater, NJ. August 2024.
17. Cresemba Prescribing Information. Astellas Pharma US., Inc. Northbrook, IL. December 2023.
18. Vfend Prescribing Information.Roerig. New York, NY. August 2024.

5 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-160448
Guideline Name	Blood Glucose Monitor & Test Strips - QL
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/11/2024	Bulk copying over Quartz Comm guidelines to Quartz EHB

Bortezomib

Prior Authorization Guideline

Guideline ID	GL-249202
Guideline Name	Bortezomib
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	10/2/2004
P&T Revision Date:	1/15/2025

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.
Drug Name: Boruzu (bortezomib)

Multiple Myeloma Indicated for the treatment of adult 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:Boruzu

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

Product Name	Generic Name	GPI	Brand/Generic
BORUZU	BORTEZOMIB INJ 3.5 MG/1.4ML	21536015002030	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Trial and failure, contraindication or intolerance to generic bortezomib

OR

2.2 For continuation of prior therapy

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:Boruzu	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BORUZU	BORTEZOMIB INJ 3.5 MG/1.4ML	21536015002030	Brand

Approval Criteria

1 - Diagnosis of mantle cell lymphoma

AND

2 - One of the following:

2.1 Trial and failure, contraindication or intolerance to generic bortezomib

OR

2.2 For continuation of prior therapy

Product Name:Brand Velcade, Generic bortezomib, Bortezomib, Boruzu	
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
BORUZU	BORTEZOMIB INJ 3.5 MG/1.4ML	21536015002030	Brand

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.
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4 . Revision History

Date	Notes
4/30/2025	Quartz Comm/EHB copied to mirrow OptumRx

Bosulif (bosutinib)

Prior Authorization Guideline

Guideline ID	GL-163395
Guideline Name	Bosulif (bosutinib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-158652
Guideline Name	Botox (onabotulinumtoxinA)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 **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

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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.
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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.
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19. Per clinical consultation with neurologist, July 20, 2015.
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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.
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Prior Authorization Guideline

Guideline ID	GL-158653
Guideline Name	Bowel Prep Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Moviprep
Colonoscopy Indicated for cleansing of the colon as a preparation for colonoscopy in adults.
Drug Name: Plenvu
Colonoscopy Indicated for cleansing of the colon in preparation for colonoscopy in adults.
Drug Name: Osmoprep
Colonoscopy Indicated for cleansing of the colon as a preparation for colonoscopy in adults.

2 . Criteria

Product Name:Brand Moviprep, Plenvu, Osmoprep	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
MOVIPREP	PEG 3350-KCL-NACL-NA SULFATE-NA ASCORBATE-C FOR SOLN 100 GM	46992006302120	Brand
PLENVU	PEG 3350-KCL-NACL-NA SULFATE-NA ASCORBATE-C FOR SOLN 140 GM	46992006302135	Brand
OSMOPREP	SOD PHOS MONO-SOD PHOS DI TABS 1.102-0.398 GM(1.5GM NA PHOS)	46109902120320	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 1 day supply within the last 180 days, contraindication, or intolerance to one of the following:

- Clenpiq
- Suprep
- Suflave

3 . References

1. Moviprep prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. June 2023.
2. Plenvu prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. September 2023.
3. Osmoprep prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. March 2019.
4. Suflave prescribing information. Sebela Pharmaceuticals, Inc. Holbrook, MA. June 2023.

Prior Authorization Guideline

Guideline ID	GL-231284
Guideline Name	Bylvay (odevixibat)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	4/2/2025

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.
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6 . Revision History

Date	Notes
4/2/2025	Copied from quartz commercial to Quartz EHB

Cablivi (caplacizumab-yhdp)

Prior Authorization Guideline

Guideline ID	GL-244309
Guideline Name	Cablivi (caplacizumab-yhdp)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	4/14/2019
P&T Revision Date:	3/19/2025

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 2024
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
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Cabometyx (cabozantinib)

Prior Authorization Guideline

Guideline ID	GL-250220
Guideline Name	Cabometyx (cabozantinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	6/22/2016
P&T Revision Date:	3/19/2025

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]

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 thyroid carcinoma (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 on February 12, 2025.
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
4/29/2025	Quartz Comm copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-288201
Guideline Name	Cabotegravir Containing Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	3/17/2021
P&T Revision Date:	4/16/2025

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*	
Diagnosis	Treatment of HIV-1 Infection
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 - 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 Vocabria 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
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand

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

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
5/29/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278207
Guideline Name	Cannabinoids
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	10/3/2006
P&T Revision Date:	4/16/2025

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.2.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed February 19, 2025.
2. Marinol prescribing information. ThePharmaNetwork, LLC. Parsippany, NJ. January 2023.
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. 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.
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. October 2022.
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
5/22/2025	Quartz guideline copied to mirrow OptumRx

Carbaglu (carglumic acid)

Prior Authorization Guideline

Guideline ID	GL-231288
Guideline Name	Carbaglu (carglumic acid)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	4/2/2025

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.

4 . Revision History

Date	Notes
4/2/2025	Copied from Quartz Comm to Quartz EHB

Prior Authorization Guideline

Guideline ID	GL-249205
Guideline Name	CGRP Inhibitors - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	5/17/2018
P&T Revision Date:	4/16/2025

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	24 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	24 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	24 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	24 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	24 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	24 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	24 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	24 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	24 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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5 . Revision History

Date	Notes
4/30/2025	Quartz Comm/EHB copied to mirrow OptumRx

Cholbam (cholic acid)

Prior Authorization Guideline

Guideline ID	GL-278208
Guideline Name	Cholbam (cholic acid)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	7/14/2015
P&T Revision Date:	4/16/2025

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 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-207296
Guideline Name	Cibinqo (abrocitinib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	3/4/2025
P&T Approval Date:	3/16/2022
P&T Revision Date:	3/15/2023

1 . Indications

Drug Name: Cibinqo (abrocitinib)
Atopic Dermatitis 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 is inadvisable. Limitations of Use: Cibinqo is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

2 . Criteria

Product Name:Cibinqo

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

Product Name	Generic Name	GPI	Brand/Generic
CIBINQO	ABROCITINIB TAB 50 MG	90272005000320	Brand
CIBINQO	ABROCITINIB TAB 100 MG	90272005000325	Brand
CIBINQO	ABROCITINIB TAB 200 MG	90272005000330	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

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 the following FDA-approved atopic dermatitis therapies:

- Dupixent (dupilumab)

AND

7 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Cibinqo may be used with concomitant topical or inhaled corticosteroids

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

Product Name	Generic Name	GPI	Brand/Generic
CIBINQO	ABROCITINIB TAB 50 MG	90272005000320	Brand
CIBINQO	ABROCITINIB TAB 100 MG	90272005000325	Brand

CIBINQO	ABROCITINIB TAB 200 MG	90272005000330	Brand

Approval Criteria

1 - Documentation of 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	*Cibinqo may be used with concomitant topical or inhaled corticosteroids

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 . 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

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6 . Revision History

Date	Notes
3/4/2025	Quartz EHB copied to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-288195
Guideline Name	Cimzia (certolizumab pegol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	5/20/2008
P&T Revision Date:	4/16/2025

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	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 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	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 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	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, 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	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 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

1. Cimzia Prescribing Information. UCB. Smyrna, GA. September 2024.
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.

5 . Revision History

Date	Notes
5/29/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-211200
Guideline Name	Clinical Duplicates Program
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

Cometriq (cabozantinib)

Prior Authorization Guideline

Guideline ID	GL-163401
Guideline Name	Cometriq (cabozantinib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. Cometriq prescribing information. Exelixis, Inc. Alameda, CA. August 2023.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. v4.2024. Available by subscription at:

https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed on September 16, 2024.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer v9.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed on September 16, 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-163402
Guideline Name	Commercial MEDLIMIT CDUR Criteria
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 prescripti ons *Note: Ask provider, "Will there be a dose escalation in the patient's o pioid utilization in the next 90 days?" If yes, approve MME level 90 dai ly 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

1. Agency Medical Directors Group. Interagency guideline on opioid dosing for chronic non-cancer pain: An educational aid to improve care and safety with opioid therapy. Available at: http://agencymeddirectors.wa.gov/Files/OpioidGdline.pdf. Accessed August 31, 2023.
2. Chou R, Fanciullo GJ, Fine PG, et al; American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain 2009; 10:113-130.
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.
4. Manchikan L, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 - Guidance. Pain Physician. 2012; 15:S67-S115.
5. Micromedex Healthcare Series. Available at http://www.thomsonhc.com/home/dispatch. Accessed August 31, 2023.
6. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1external icon.

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-278210
Guideline Name	Constipation Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	8/18/2008
P&T Revision Date:	4/16/2025

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:Trulance	
Approval Length	12 month(s)

Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TRULANCE	PLECANATIDE TAB 3 MG	52543060000320	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 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to generic lubiprostone

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

Product Name	Generic Name	GPI	Brand/Generic
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 - Trial (of a minimum 30 days supply) or intolerance to generic prucalopride

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. May 2024.
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. March 2024.
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
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-165054
Guideline Name	Continuous Glucose Monitors, Sensors, and Transmitters - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/12/2025
P&T Approval Date:	
P&T Revision Date:	3/20/2024

1 . Criteria

Product Name:Dexcom 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

DEXCOM G6 SENSOR	*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

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 “PFEHBCGMPA”

Product Name:Dexcom 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
DEXCOM G6 SENSOR	*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

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 “PFEHBCGMPA”

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	*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
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 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

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 Minimum 90 day trial within the last 180 days, to Dexcom Products (Applies to all products except Dexcom)

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 TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN LINK 3	*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
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 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

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 Dexcom Products (Applies to all products except Dexcom)

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
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	*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
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 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
BIGFOOT UNITY PROGRAM KIT	*BLOOD GLUCOSE MONITOR KIT W/ MONITOR DEVICE & DIGITAL APP**	97202010006419	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 Submission of medical records (e.g., chart notes) or paid claims confirming minimum 90 day trial within the last 180 days, to Dexcom products (Applies to all products except Dexcom)

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.

4 . Revision History

Date	Notes
2/12/2025	Quartz EHB copied to mirrow Optum EHB.

Prior Authorization Guideline

Guideline ID	GL-278213
Guideline Name	Copper Chelating Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	8/20/2014
P&T Revision Date:	4/16/2025

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., 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., 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
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-162301
Guideline Name	Cosentyx (secukinumab) - PA
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 section 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

Prior Authorization Guideline

Guideline ID	GL-163411
Guideline Name	Coverage of Off-Label Non-FDA Approved Indications
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 such 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-244310
Guideline Name	Darzalex (daratumumab), Darzalex Faspro (daratumumab and hyaluronidase-fihj) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	1/27/2016
P&T Revision Date:	2/20/2025

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 for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. **Multiple Myeloma - Combination therapy** Indicated in combination with 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 for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

Multiple Myeloma - Combination Indicated in combination with 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 for the treatment of 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. July 2024.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Multiple Myeloma v1.2025. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed January 9, 2025.
3. Darzalex Faspro Prescribing Information. Janssen Biotech, Inc. Horsham, PA. July 2024.

4 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Demser (metyrosine)

Prior Authorization Guideline

Guideline ID	GL-244311
Guideline Name	Demser (metyrosine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	
P&T Revision Date:	3/19/2025

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. July 2021.
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
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-241256
Guideline Name	Diabetic GLP-1 Agonists
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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

Dibenzyline (phenoxybenzamine)

Prior Authorization Guideline

Guideline ID	GL-244312
Guideline Name	Dibenzyline (phenoxybenzamine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	3/16/2022
P&T Revision Date:	3/19/2025

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. December 2024.

5 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163538
Guideline Name	Dichlorphenamide Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-165055
Guideline Name	DPP-4 Inhibitors
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/12/2025
P&T Approval Date:	2/20/2007
P&T Revision Date:	6/19/2024

1 . Indications

Drug Name: Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/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) 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: 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.

2 . Criteria

Product Name:Janumet, Janumet XR, Januvia, 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
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 5-1000 MG	27992502407530	Brand
JENTADUETO XR	LINAGLIPTIN-METFORMIN HCL TAB ER 24HR 2.5-1000 MG	27992502407520	Brand
TRADJENTA	LINAGLIPTIN TAB 5 MG	27550050000320	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 generic metformin

3 . References

1. Janumet Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2022.
2. Janumet XR Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2022.
3. Januvia Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2023.
4. Jentadueto Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.
5. Jentadueto XR Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.
6. Tradjenta Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.

4 . Revision History

Date	Notes
2/12/2025	Quartz EHB copied to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-288202
Guideline Name	Dupixent (dupilumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	11/17/2016
P&T Revision Date:	4/16/2025

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 ONE of the following [2]:

- Medium or higher potency topical corticosteroid
- Generic topical calcineurin inhibitor (e.g., tacrolimus ointment)
- Eucrisa (crisaborole) ointment
- Opzelura (ruxolitinib) cream
- Vtama (tapinarof) cream
- Zoryve (roflumilast) 0.15% cream

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

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	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

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

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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
5/29/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-285189
Guideline Name	Eculizumab Products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	11/19/2014
P&T Revision Date:	4/16/2025

1 . Indications

Drug Name: Bkemv (eculizumab-aeeb)
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: Bkemv 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. **Off Label Uses: 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.
Drug Name: Epysqli (eculizumab-aagh)
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: Epysqli is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). **Off Label Uses: Generalized Myasthenia Gravis (gMG)** Indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients six years of age and older 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.
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 generalized myasthenia gravis (gMG) in adult and pediatric patients six years of age and older 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:Bkemv, Epysqli, 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
BKEMV	ECULIZUMAB-AEEB IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050012020	Brand
EPYSQLI	ECULIZUMAB-AAGH IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050022020	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:Bkemv, Epysqli, 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
BKEMV	ECULIZUMAB-AEEB IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050012020	Brand

EPYSQLI	ECULIZUMAB-AAGH IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050022020	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:Bkemv, Epysqli, 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
BKEMV	ECULIZUMAB-AEEB IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050012020	Brand
EPYSQLI	ECULIZUMAB-AAGH IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050022020	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:Bkemv, Epysqli, 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
BKEMV	ECULIZUMAB-AEEB IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050012020	Brand
EPYSQLI	ECULIZUMAB-AAGH IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050022020	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:Bkemv, Epysqli [off-label], 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
BKEMV	ECULIZUMAB-AEEB IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050012020	Brand
EPYSQLI	ECULIZUMAB-AAGH IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050022020	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - Patient is 6 years of age or older

AND

4 - Trial and failure, contraindication (e.g., age), or intolerance to one of the following:

- Ultomiris (ravulizumab)
- Vyvgart (efgartigimod)

AND

5 - One of the following: [2, 3]

5.1 For patients between 6 and 17 years of age, trial and failure, contraindication, or intolerance to one of the following:

- Immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)
- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

OR

5.2 For patients 18 years of age or older, one of the following:

5.2.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

5.2.2 Both of the following:

5.2.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

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

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Bkemv, Epysqli [off-label], 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
BKEMV	ECULIZUMAB-AEEB IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050012020	Brand
EPYSQLI	ECULIZUMAB-AAGH IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050022020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and failure, contraindication (e.g., age), or intolerance to one of the following:

- Ultomiris (ravulizumab)
- Vyvgart (efgartigimod)

Product Name:Bkemv, Epysqli [off-label], Soliris [off-label]	
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
BKEMV	ECULIZUMAB-AEEB IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050012020	Brand
EPYSQLI	ECULIZUMAB-AAGH IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050022020	Brand

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

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

- Neurologist
- Ophthalmologist

Product Name:Bkemv, Epysqli [off-label], Soliris [off-label]	
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
BKEMV	ECULIZUMAB-AEEB IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050012020	Brand
EPYSQLI	ECULIZUMAB-AAGH IV SOLN 300 MG/30ML (10 MG/ML)(FOR INFUSION)	85805050022020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

3 . References

1. Soliris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. February 2025.
2. 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.
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.
4. Bkemv Prescribing Information. Amgen Inc. Thousand Oaks, CA. October 2024.
5. Epysqli Prescribing Information. Samsung Bioepis Co., Ltd. Incheon, Republic of Korea. July 2024.

4 . Revision History

Date	Notes
5/29/2025	Quartz guideline copied to mirrow OptumRx

Elmiron (pentosan polysulfate sodium)

Prior Authorization Guideline

Guideline ID	GL-158686
Guideline Name	Elmiron (pentosan polysulfate sodium)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Elmiron (pentosan polysulfate sodium)
Interstitial Cystitis Indicated for the relief of bladder pain or discomfort associated with interstitial cystitis.

2 . Criteria

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

Product Name	Generic Name	GPI	Brand/Generic
ELMIRON	PENTOSAN POLYSULFATE SODIUM CAPS 100 MG	56500060100110	Brand

Approval Criteria

1 - Diagnosis of interstitial cystitis

AND

2 - Patient has bladder pain or discomfort

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to two of the following: [2]

- Amitriptyline
- Cimetidine
- Hydroxyzine

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

Product Name	Generic Name	GPI	Brand/Generic
ELMIRON	PENTOSAN POLYSULFATE SODIUM CAPS 100 MG	56500060100110	Brand

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Elmiron Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. June 2020.
2. Hanno PM, Erickson D, Moldwin R, et al. Diagnosis and treatment of interstitial cystitis/bladder pain syndrome: AUA guideline amendment. J Urol . 2015 May;193(5):1545-53. doi: 10.1016/j.juro.2015.01.086.

Prior Authorization Guideline

Guideline ID	GL-278217
Guideline Name	Emflaza (deflazacort) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	4/26/2017
P&T Revision Date:	4/16/2025

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 Presence 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 with expertise in the treatment of DMD

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 Presence 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 with expertise in the treatment of DMD

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 2024.
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
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-285194
Guideline Name	Enbrel (etanercept)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	5/15/2005
P&T Revision Date:	4/16/2025

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. September 2024.

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4 . Revision History

Date	Notes
5/29/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278222
Guideline Name	Ergot Alkaloids
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	4/15/2020
P&T Revision Date:	4/16/2025

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

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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.
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5 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163543
Guideline Name	Erythropoietic Agents - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

Product Name:Aranesp, Epogen, Mircera, Procrit, or Retacrit	
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]

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

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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.

Evrysdi (risdiplam)

Prior Authorization Guideline

Guideline ID	GL-244313
Guideline Name	Evrysdi (risdiplam)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	10/21/2020
P&T Revision Date:	3/19/2025

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
EVRYSDI	RISDIPLAM TAB 5 MG	74706560000320	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
EVRYSDI	RISDIPLAM TAB 5 MG	74706560000320	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. February 2025.
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.
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5 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Eysuvis (loteprednol etabonate ophthalmic suspension)

Prior Authorization Guideline

Guideline ID	GL-278226
Guideline Name	Eysuvis (loteprednol etabonate ophthalmic suspension)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	2/18/2021
P&T Revision Date:	4/16/2025

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.
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4 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163469
Guideline Name	Fabry Disease Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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.
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. Elfabrio prescribing information. Chiesi USA, Inc. Cary, NC. May 2023.

6. UptoDate. Fabry disease:Treatment and prognosis. Available at: https://www.uptodate.com/contents/fabry-disease-treatment-and-prognosis?search=fabry%20disease&source=search_result&selectedTitle=2~68&usage_type=default&display_rank=2. Accessed September 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-249206
Guideline Name	Fecal Microbiota Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	2/16/2023
P&T Revision Date:	2/20/2025

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. ZINPLAVA is not an antibacterial drug. ZINPLAVA should only be used in conjunction with antibacterial drug 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: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 - Submission of medical records (e.g., chart notes) confirming 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. June 2024.
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.
6. Debast SB, Bauer MP, Kuijper EJ. European Society of Clinical Microbiology and Infectious Diseases: update of the treatment guidance document for Clostridium difficile infection. Clin Microbiol Infect. 2014;20 Suppl 2:1-26.
7. Zinplava Product Dossier. Merck and Co., Inc. May 2023.
8. Vincent Y, Manji A, Grgory-Miller K, et al. A review or management of Clostridium difficile infection: Primary and recurrence. Antibiotics. 2015;4(4):411-423.
9. Kelsen JR, Kim J, Latta D, et al. Recurrence rate of Clostridium difficile infection in hospitalized patients with inflammatory bowel disease. Inflamm Bowel Disease. 2011;17:50-55.

10. Kelly CP. Can we identify patients at high risk of recurrent Clostridium difficile infection? Clin Microbiol Infect. 2012;18 Suppl 6:21-27.
11. Per clinical consult with gastroenterologist, December 28, 2016.

5 . Revision History

Date	Notes
4/30/2025	Quartz Comm/EHB copied to mirrow OptumRx

Ferriprox (deferiprone)

Prior Authorization Guideline

Guideline ID	GL-278227
Guideline Name	Ferriprox (deferiprone)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	4/10/2012
P&T Revision Date:	4/16/2025

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 demonstrates positive clinical response to therapy (e.g., 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
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278229
Guideline Name	Fibric Acid Derivatives
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	
P&T Revision Date:	4/16/2025

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 (of a minimum 30 day supply) or intolerance 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.

4 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Gamifant (emapalumab-lzsg)

Prior Authorization Guideline

Guideline ID	GL-244314
Guideline Name	Gamifant (emapalumab-lzsg)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	
P&T Revision Date:	3/19/2025

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 2023.
2. Per clinical consult with a pediatric hematologist/oncologist, January 18, 2019.
3. Wu Y, et al. Hemophagocytic lymphohistiocytosis: current treatment advances, emerging targeted therapy and underlying mechanisms. Journal of Hematology & Oncology. 2024; 17:106.

5 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Gattex (teduglutide)

Prior Authorization Guideline

Guideline ID	GL-211201
Guideline Name	Gattex (teduglutide)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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-163941
Guideline Name	Gaucher Disease Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

Prior Authorization Guideline

Guideline ID	GL-249207
Guideline Name	Gaucher Disease Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	11/20/2000
P&T Revision Date:	3/19/2025

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), Generic 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). **Off Label Uses: Niemann-Pick disease type C (NPC)** Indicated for use in combination with Miplyffa (arimoclomol) for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older. [9-11]

2 . Criteria

Product Name:Cerezyme, Elelyso, or VPRIV	
Diagnosis	Type 1 Gaucher Disease
Approval Length	24 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	
Diagnosis	Type 1 Gaucher Disease
Approval Length	24 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	24 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	
Diagnosis	Type 1 Gaucher Disease
Approval Length	24 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZAVESCA	MIGLUSTAT CAP 100 MG	82700070000120	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming 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)

Product Name:Brand Zavesca	
Diagnosis	Niemann-Pick disease type C (NPC) (off-label) [E]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZAVESCA	MIGLUSTAT CAP 100 MG	82700070000120	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming 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

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 2024.
2. Elelyso Prescribing Information. Pfizer, Inc. New York, NY. July 2024.
3. VPRIV Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Cambridge, MA. September 2024.
4. Cerdelga Prescribing Information. Genzyme Corporation. Cambridge, MA. January 2024.
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. Celebration, FL. 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.
15. Miglustat Prescribing Information. ANI Pharmaceuticals, Inc. Baudette, MN. August 2022.

5 . Revision History

Date	Notes
4/30/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278231
Guideline Name	Generic-First Step Program
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	11/14/2019
P&T Revision Date:	4/16/2025

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
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
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
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
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
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

Product Name	Gpi
ABILIFY	592500150003**
ACZONE	900510150040**
ALPHAGAN P SOLN 0.1%	86602020102005

ALTACE	361000500001**
ARIMIDEX	21402810000310
ARTHROTEC 50	661099022006**
ARTHROTEC 75 TAB	66109902200630
ATACAND	361500201003**
AVAPRO	361500300003**
AVODART CAP 0.5MG	56851020000120
AZOPT	86802320001820
BROVANA 15MCG/2ML	44201012102520
BYSTOLIC	332000401003**
CANASA SUP 1000MG	52500030005240
CARBATROL	726000200069**
CARDIZEM LA	340000101075**
CARNITOR SOL 1GM/10ML	30903045102010
CARNITOR TAB 330MG	30903045100330
CATAPRES-TTS	362010100088**
CELEXA	581600201003**
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
COMBIGAN 0.2%/0.5% SOLN	86259902152020
COREG	333000070003**
COREG CR	333000072070**
CORTEF	221000250003**
COSOPT PF SOL	86259902202060
COSOPT SOL 22.3-6.8	86259902202020
COZAAR	361500402003**
DELESTROGEN INJ	240000352017**
DEPAKOTE	725000101006**
DEPAKOTE ER	725000101075**
DEPAKOTE SPR CAP 125MG	7250001010H120
DILANTIN-125	72200030001810
EFFEXOR XR 37.5 MG	58180090107020
EFFEXOR XR 150 MG	58180090107050
EFFEXOR XR 75 MG	58180090107030
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
GOLYTELY	469920053021**
HALOG	90550070003710
HYZAAR	369940024503**

IMITREX INJ	6740607010D520
IMITREX INJ	6740607010E2**
IMITREX INJ	6740607010D510
IMITREX INJ 4MG/0.5	6740607010D510
IMITREX INJ 6MG/0.5	6740607010D520
IMITREX TABLET	674060701003**
IMITREX 20MG SPRAY	67406070002040
IMITREX 5MG SPRAY	67406070002010
INDERAL LA CAP	331000401070**
KEPPRA XR	726000430075**
KEPPRA	726000430003**
KEPPRA SOL 100MG/ML	72600043002020
KLONOPIN	721000100003**
K-TAB	797000300004**
LAMICTAL	726000400003**
LAMICTAL ODT	726000400072**
LAMICTAL ODT KIT	72600040006450
LAMICTAL ODT KIT	72600040006455
LAMICTAL ODT KIT	72600040006460
LAMICTAL XR	726000400075**
LAMICTAL KIT	72600040006435
LAMICTAL	726000400005**
LAMICTAL KIT START 35	72600040006420
LAMICTAL KIT START 49	72600040006430
LASIX	372000300003**
LATISSE	90734020002020

LATUDA	594000231003**
LOESTRIN 21 TAB 1.5/30	25990002600320
LOESTRIN FE TAB 1.5/30	25990003610320
LOESTRIN FE TAB 1/20	25990003610310
LOESTRIN TAB 1/20-21	25990002600310
LOTREL	369915022001**
LYRICA	726000570001**
LYRICA SOL 20MG/ML	72600057002020
MAXALT	67406060100320
MAXALT-MLT	67406060107230
MICARDIS	361500700003**
MICARDIS HCT	369940026003**
NALFON TAB 600MG	66100010100305
NALFON CAP 400MG	66100010100120
NATROBA SUS 0.9%	90900048001820
NEURONTIN 600MG TAB	72600030000330
NEURONTIN 800MG TAB	72600030000340
NEURONTIN CAP	726000300001**
NEURONTIN SOL 250/5ML	72600030002020
NITROSTAT	321000300007**
PAXIL CR	581600600075**
PAXIL	581600600003**
PLAQUENIL	130000201003**
PLAVIX	851580201003**
PRED FORTE SUS 1% OP	86300050101815
PREDNISOLONE ACETATE P- F	86300050101815

PROMETRIUM CAP	260000400001**
PROPECIA	90736030000310
QUESTRAN	391000100029**
QUESTRAN	391000100030**
RANEXA	322000400074**
RELPAX	674060251003**
RENAGEL	528000701003**
RESTORIL	602010300001**
RISPERDAL CONSTA	5907007010G2**
RISPERDAL TAB	590700700003**
RISPERDAL SOL 1MG/ML	59070070002010
SAFYRAL TAB	25990003200330
SEASONIQUE TAB	25993002300330
SEROQUEL XR	591530701075**
SEROQUEL	591530701003**
SILVADENE CRE 1%	90450030003710
SOMA	751000200003**
SOVUNA	130000201003**
SUBOXONE MIS 12-3MG	65200010208250
SUBOXONE MIS 2-0.5MG	65200010208220
SUBOXONE MIS 4-1MG	65200010208230
SUBOXONE MIS 8-2MG	65200010208240
TEGRETOL SUS 100/5ML	72600020001810
TEGRETOL TAB 200MG	72600020000305
TEGRETOL-XR	726000200074**
TENORMIN	332000200003**

TIKOSYN	354000250001**
TIMOPTIC OCU SOL 0.25% OP	86250030102006
TIMOPTIC OCU SOL 0.5% OP	86250030102011
TIMOPTIC SOL 0.25% OP	86250030102005
TIMOPTIC SOL 0.5% OP	86250030102010
TIMOPTIC-XE SOL 0.25% OP	86250030107620
TIMOPTIC-XE SOL 0.5% OP	86250030107630
TOPAMAX SPR	726000750068**
TOPAMAX	726000750003**
TOPICORT	90550040000910
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	751000200003**
VECTICAL OIN 3MCG/GM	90250028004220
VESICARE	541000552003**
VIGAMOX DRO 0.5%	86101038102020
VIMPAT	726000360003**
VIMPAT	726000360020**
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**
ZOLOFT	581600701003**
ZONEGRAN	726000900001**
ZOVIRAX	90350010004205
ZOVIRAX CRE 5%	90350010003720
ZYPREXA	591570600003**
ZYPREXA INJ 10MG	59157060002120

3 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163554
Guideline Name	Gilenya (fingolimod) - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 changes to criteria.

Gilotrif (afatinib)

Prior Authorization Guideline

Guideline ID	GL-163396
Guideline Name	Gilotrif (afatinib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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-278232
Guideline Name	Glycopyrrolate Oral Solution
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	3/16/2022
P&T Revision Date:	4/16/2025

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 One of the following:

4.2.1 Patient is unable to swallow a solid dosage form (e.g., oral tablet) 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

4.2.2 Dosage requirements cannot be met with a solid dosage form

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 One of the following:

2.2.1 Patient is unable to swallow a solid dosage form (e.g., oral tablet) 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

2.2.2 Dosage requirements cannot be met with a solid dosage form

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. Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY. January 2024.
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.

5 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163610
Guideline Name	Gonadotropin-Releasing Hormone Agonists
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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

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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.
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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.
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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 EHB to mirrow Quartz COM with no cha nges to criteria.

Prior Authorization Guideline

Guideline ID	GL-162304
Guideline Name	Growth Hormones - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 expected 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 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	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 exp ected 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 expected adult height will be required for renewal.*Approve at NDC list "SOMATROPPA".

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 expected 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 exp ected adult height will be required for renewal.*Approve at NDC list "S OMATROPPA".

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)

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]

3 . References

1. Genotropin Prescribing Information. Pharmacia & Upjohn Co, a Division of Pfizer Inc. New York, NY. April 2019.
2. Humatrope Prescribing Information. Eli Lilly and Company. Indianapolis, IN. December 2023.
3. Norditropin Flexpro Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. March 2020.
4. Nutropin AQ NuSpin Prescribing Information. Genentech, Inc. South San Francisco, CA. December 2016.
5. Omnitrope Prescribing Information. Sandoz Inc. Princeton, NJ. March 2024.
6. Saizen Prescribing Information. EMD Serono, Inc. Rockland, MA. February 2020.
7. Serostim Prescribing Information. EMD Serono, Inc. Rockland, MA. June 2019.
8. Zomacton Prescribing Information. Ferring Pharmaceuticals Inc. Parsippany, NJ. April 2024.
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4 . Revision History

Date	Notes
12/20/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-244206
Guideline Name	Halcinonide cream
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	7/21/2021
P&T Revision Date:	3/19/2025

1 . Indications

Drug Name: Halcinonide cream
Corticosteroid-responsive dermatoses Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

2 . Criteria

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

Product Name	Generic Name	GPI	Brand/Generic
HALCINONIDE	HALCINONIDE CREAM 0.1%	90550070003710	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 three of the following generics:

- betamethasone dipropionate 0.05% ointment
- betamethasone augmented 0.05% cream
- desoximetasone 0.25% cream
- fluocinonide 0.05% solution
- fluocinonide 0.05% cream
- fluocinonide 0.05% gel
- fluocinonide 0.05% ointment

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4 . Revision History

Date	Notes
4/24/2025	Quartz guideline copied to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-160577
Guideline Name	Healthcare Reform Copay Waiver Review
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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
11/13/2024	New program

Prior Authorization Guideline

Guideline ID	GL-160444
Guideline Name	Healthcare Reform Copay Waiver Review - Contraceptives
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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
11/11/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-286222
Guideline Name	Hemlibra (Emicizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025

1 . Criteria

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

Product Name	Generic Name	GPI	Brand/Generic
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 12 MG/0.4ML (30 MG/ML)	85105030202007	Brand
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 30 MG/ML	85105030202010	Brand

HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 60 MG/0.4ML (150 MG/ML)	85105030202020	Brand
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 105 MG/0.7ML (150 MG/ML)	85105030202030	Brand
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 150 MG/ML	85105030202040	Brand
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 300 MG/2ML (150 MG/ML)	85105030202060	Brand

Approval Criteria

1 - Diagnosis of congenital hemophilia A

AND

2 - One of the following:

2.1 ALL of the following:

2.1.1 Hemophilia A with inhibitors to Factor VIII

AND

2.1.2 Member requires prophylaxis to prevent or reduce bleeding episodes

AND

2.1.3 One of the following:

- Not used in combination with Immune Tolerance Induction (ITI) therapy
- Member is currently on a bypassing agent (NovoSeven, FEIBA)

OR

2.2 BOTH of the following:

2.2.1 Hemophilia A without inhibitors

AND

2.2.2 One of the following:

- Member requires prophylaxis to prevent or reduce bleeding episodes despite optimal dose/frequency of Factor VIII product
- Member is unable to administer prophylaxis based on individual patient factors (e.g., IV access, home administration, etc.)

AND

3 - Member is followed by a plan approved bleeding disorders program

AND

4 - Drug will not be used in combination with other monoclonal antibodies for hemophilia

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

Product Name	Generic Name	GPI	Brand/Generic
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 12 MG/0.4ML (30 MG/ML)	85105030202007	Brand
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 30 MG/ML	85105030202010	Brand
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 60 MG/0.4ML (150 MG/ML)	85105030202020	Brand
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 105 MG/0.7ML (150 MG/ML)	85105030202030	Brand
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 150 MG/ML	85105030202040	Brand
HEMLIBRA	EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 300 MG/2ML (150 MG/ML)	85105030202060	Brand

Approval Criteria **1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

2 . Revision History

Date	Notes
6/10/2025	New program

Prior Authorization Guideline

Guideline ID	GL-164805
Guideline Name	Hereditary Angioedema Agents - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/5/2025
P&T Approval Date:	2/17/2009
P&T Revision Date:	4/17/2024

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: 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: 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.

2 . Criteria

Product Name:Cinryze	
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

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A]:

2.1 Diagnosis has been confirmed by 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 Patient has 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 FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen 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 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name:Cinryze	
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

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], Sajazir	
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
SAJAZIR	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Generic
SAJAZIR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A]:

2.1 Diagnosis has been confirmed by 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 Patient has 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 FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen 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 18 years of age or older (applies to Sajazir only)

AND

6 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name:Cinryze [off-label], Sajazir	
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
SAJAZIR	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Generic
SAJAZIR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic

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) [3, A]

AND

2 - One of the following [A]:

2.1 Diagnosis has been confirmed by 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 Patient has 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 FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen 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 - 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:Haegarda, Orladeyo or Takhzyro	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
HAEGARDA	C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 2000 UNIT	85802022002130	Brand
HAEGARDA	C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 3000 UNIT	85802022002140	Brand
ORLADEYO	BEROTRALSTAT HCL CAP 110 MG	85840010200120	Brand
ORLADEYO	BEROTRALSTAT HCL CAP 150 MG	85840010200130	Brand
TAKHZYRO	LANADELUMAB-FLYO SOLN PREF SYRINGE 150 MG/ML	8584204020E510	Brand
TAKHZYRO	LANADELUMAB-FLYO SOLN PREF SYRINGE 300 MG/2ML (150 MG/ML)	8584204020E520	Brand
TAKHZYRO	LANADELUMAB-FLYO INJ 300 MG/2ML (150 MG/ML)	85842040202020	Brand

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - Submission of medical records (e.g., chart notes) confirming one of the following [A]:

2.1 Diagnosis has been confirmed by 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 Patient has 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 FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen 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 - Submission of medical records (e.g., chart notes) or absence of paid claims confirming drug is 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 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 (Applies to Haegarda and Takhzyro only):

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication or intolerance to Cinryze

OR

6.2 Both of the following:

- 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
- Patient demonstrates positive clinical response to therapy

AND

7 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name:Firazyr, Kalbitor, Ruconest	
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
KALBITOR	ECALLANTIDE INJ 10 MG/ML	85840030002020	Brand
RUCONEST	C1 ESTERASE INHIBITOR (RECOMBINANT) FOR IV INJ 2100 UNIT	85802022102130	Brand

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - Submission of medical records (e.g., chart notes) confirming one of the following [A]:

2.1 Diagnosis has been confirmed by 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 Patient has 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 FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen 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 - Submission of medical records (e.g., chart notes) or absence of paid claims confirming drug is not used in combination with other approved treatments for acute HAE attacks

AND

5 - One of the following:

- Patient is 18 years of age or older (applies to Firazyr only)
- Patient is 12 years of age or older (applies to Kalbitor only)

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, or intolerance to one of the following:

- generic icatibant
- Sajazir

AND

6.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, or intolerance to Berinert

OR

6.2 Both of the following:

- 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
- Patient demonstrates positive clinical response to therapy

AND

7 - 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]

4 . References

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5 . Revision History

Date	Notes
2/5/2025	Quartz EHB to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-244315
Guideline Name	High Cost, Low Value Non-Formulary Program
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	
P&T Revision Date:	2/20/2025

Note:

For off-label use, do not review against the off-label administration guideline. Deny per guideline criteria.

1 . Criteria

Product Name:A Non-Preferred Non-Formulary or Excluded Medication* (Brand Absorica, Absorica LD, Brand Aczone, Brand Adapalene 0.1% pads, Brand 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, Brand Duexis, Epiceram, generic fenoprofen calcium, Flector, Fluovix, Folic-K, Genicin Vita-S, Brand Inderal XL, Innopran XL, generic ibuprofen-famotidine, 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
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) 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
Brand Duexis, generic ibuprofen/famotidine	**NSAID** / **ANTI-ULCER AGENT** Diclofenac / cimetidine Indomethacin / famotidine Ibuprofen / nizatidine

	Ketoprofen ranitidine Naproxen Meloxicam Nabumetone Piroxicam Sulindac
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	
Brand Vimovo, generic naproxen/esomeprazole	**NSAID**	**ANTI-ULCER AGENT**
	Diclofenac	Esomeprazole
	Indomethacin	Lansoprazole
	Ketoprofen	Omeprazole
	Naproxen	Rabeprazole
	Meloxicam	Pantoprazole
	Nabumetone	
	Piroxicam	
	Sulindac	

Winlevi	Generic adapalene (cream, gel, lotion) Generic tretinoin containing products Generic tazarotene cream Generic single-agent clindamycin product Generic Dapsone gel	
Xerese	Acyclovir 5% Cream Acyclovir (oral) Famciclovir (oral) Hydrocortisone 1% Cream Penciclovir cream Valacyclovir (oral)	
Xhance	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	
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
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163201
Guideline Name	Human Chorionic Gonadotropin (hCG)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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.

Iclusig (ponatinib)

Prior Authorization Guideline

Guideline ID	GL-163428
Guideline Name	Iclusig (ponatinib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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.

Prior Authorization Guideline

Guideline ID	GL-160451
Guideline Name	Ilaris (canakinumab injection)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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
11/11/2024	Bulk copying over Quartz Comm guidelines to Quartz EHB

Prior Authorization Guideline

Guideline ID	GL-220217
Guideline Name	Imatinib Products - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	8/24/2001
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Gleevec (imatinib mesylate), Imkeldi
Chronic myelogenous/myeloid leukemia (CML) 1) Indicated for the treatment of newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase. 2) 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)** 1) Indicated for the treatment of adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). 2) 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) 1) Indicated for the treatment of patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). 2) 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:Imkeldi	
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
IMKELDI	IMATINIB MESYLATE ORAL SOLN 80 MG/ML (BASE EQUIVALENT)	21531835102020	Brand

Approval Criteria

1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)

AND

2 - Patient is unable to swallow generic imatinib tablet 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: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:Imkeldi	
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
IMKELDI	IMATINIB MESYLATE ORAL SOLN 80 MG/ML (BASE EQUIVALENT)	21531835102020	Brand

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL)

AND

2 - Patient is unable to swallow generic imatinib tablet 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: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:Imkeldi	
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
IMKELDI	IMATINIB MESYLATE ORAL SOLN 80 MG/ML (BASE EQUIVALENT)	21531835102020	Brand

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

AND

2 - Patient is unable to swallow generic imatinib tablet 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: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:Imkeldi	
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
IMKELDI	IMATINIB MESYLATE ORAL SOLN 80 MG/ML (BASE EQUIVALENT)	21531835102020	Brand

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - Patient is unable to swallow generic imatinib tablet 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: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:Imkeldi

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
IMKELDI	IMATINIB MESYLATE ORAL SOLN 80 MG/ML (BASE EQUIVALENT)	21531835102020	Brand

Approval Criteria

1 - Diagnosis of at least one of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - Patient is unable to swallow generic imatinib tablet 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: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:Imkeldi	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMKELDI	IMATINIB MESYLATE ORAL SOLN 80 MG/ML (BASE EQUIVALENT)	21531835102020	Brand

Approval Criteria

1 - Diagnosis of unresectable, recurrent, or metastatic dermatofibrosarcoma protuberans (DFSP)

AND

2 - Patient is unable to swallow generic imatinib tablet 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: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:Imkeldi	
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
IMKELDI	IMATINIB MESYLATE ORAL SOLN 80 MG/ML (BASE EQUIVALENT)	21531835102020	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Patient is unable to swallow generic imatinib tablet 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:Brand Gleevec, Generic imatinib, Imkeldi	
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
IMKELDI	IMATINIB MESYLATE ORAL SOLN 80 MG/ML (BASE EQUIVALENT)	21531835102020	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
2. Imkeldi Prescribing Information. Shorla Oncology Inc. Cambridge, MA 02142, USA. November 2024

4 . Revision History

Date	Notes
3/18/2025	Quartz guideline copied to mirrow Optum standard and EHB

Prior Authorization Guideline

Guideline ID	GL-163414
Guideline Name	Increlex (mecasermin [rDNA origin])
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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.
3. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. Horm Res Paediatr. 2016;86:361-397. Available at: https://www.karger.com/Article/Pdf/452150. Accessed November 1, 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-285190
Guideline Name	Inhaled Corticosteroids - ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	2/18/2015
P&T Revision Date:	4/16/2025

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 4 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	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand

120 METERED DOSES			
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. Examples of when a spacer may be necessary include challenges with:

- 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. Examples of when a spacer may be necessary include challenges with:

- 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 2024. Updated July 2024. Available from www.ginaasthma.org

5 . Revision History

Date	Notes
5/29/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163415
Guideline Name	Interstitial Lung Disease (ILD) Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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.

Prior Authorization Guideline

Guideline ID	GL-165169
Guideline Name	Intrarosa (prasterone)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/14/2025
P&T Approval Date:	7/21/2021
P&T Revision Date:	6/19/2024

1 . Indications

Drug Name: Intrarosa (prasterone)
Moderate to Severe Dyspareunia Indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

2 . Criteria

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

Product Name	Generic Name	GPI	Brand/Generic
INTRAROSA	PRASTERONE VAGINAL INSERT 6.5 MG	55400055009920	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), contraindication, or intolerance to one of the following:

- Premarin vaginal cream
- Osphena

3 . References

1. Intrarosa prescribing information. AMAG Pharmaceuticals, Inc. Waltham, MA. February 2018.

4 . Revision History

Date	Notes
2/14/2025	Quartz EHB copied to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-244316
Guideline Name	Jakafi (ruxolitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/21/2012
P&T Revision Date:	3/19/2025

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
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Jevtana (cabazitaxel)

Prior Authorization Guideline

Guideline ID	GL-244317
Guideline Name	Jevtana (cabazitaxel)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/15/2011
P&T Revision Date:	3/19/2025

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.

4 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-249308
Guideline Name	Kalydeco (ivacaftor)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025

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	When approved; no reauthorization required
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.

	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

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: 2/4/25]

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. June 2024.
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
5/1/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx/EHB

Prior Authorization Guideline

Guideline ID	GL-160452
Guideline Name	Kineret (anakinra)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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
11/11/2024	Bulk copying over Quartz Comm guidelines to Quartz EHB

Prior Authorization Guideline

Guideline ID	GL-162133
Guideline Name	Kisqali (ribociclib), Kisqali Femara Co-Pack (letrozole and ribociclib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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-163545
Guideline Name	Lenvima (lenvatinib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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	LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE)	2133505420B250	Brand

DAILY DOSE			

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-160456
Guideline Name	Long Acting Insulins - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/15/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-278233
Guideline Name	Long-Acting Bronchodilator Combinations - PA, ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	10/5/2010
P&T Revision Date:	4/16/2025

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. Examples of when a spacer may be necessary include challenges with:

- 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. Examples of when a spacer may be necessary include challenges with:

- 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. April 2024.
5. Duaklir Pressair Prescribing Information. Circassia Pharmaceuticals Inc. Morrisville, NC. January 2022.
6. Wixela inhub Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. August 2022
7. Symbicort Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. July 2019.

8. Breyna Prescribing Information. Mylan Pharmaceuticals, Inc. Morgantown, WV. September 2020.

4 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-244319
Guideline Name	Lynparza (olaparib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/18/2015
P&T Revision Date:	3/19/2025

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
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Mekinist (trametinib)

Prior Authorization Guideline

Guideline ID	GL-244320
Guideline Name	Mekinist (trametinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	7/9/2013
P&T Revision Date:	3/19/2025

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, as detected by an FDA-approved test, 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.2025. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed March 4, 2025.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer v.3.2025. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 4, 2025.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma v.5.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed March 4, 2025.

5 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278234
Guideline Name	Migraine Quantity Limit
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	5/19/2016
P&T Revision Date:	4/16/2025

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 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

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5. Imitrex Nasal Spray Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2017.
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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.
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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
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-164956
Guideline Name	Multiple Sclerosis (MS) Agents - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/10/2025
P&T Approval Date:	11/20/2000
P&T Revision Date:	11/21/2024

1 . Indications

Drug Name: Aubagio (teriflunomide)
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: Avonex (interferon beta-1a)
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.
Drug Name: Bafiertam (monomethyl 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.
Drug Name: Betaseron (interferon beta-1b)
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.
Drug Name: Copaxone (glatiramer acetate), Glatopa (glatiramer acetate)
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.
Drug Name: Extavia (interferon beta-1b)
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.
Drug Name: Kesimpta (ofatumumab)
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.
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: Mayzent (siponimod)

Relapsing forms of MS Indicated for the treatment of relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Ocrevus (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: Plegridy (peginterferon beta-1a)
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.
Drug Name: Ponvory (ponesimod)
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.
Drug Name: Rebif (interferon beta-1a)
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.
Drug Name: Vumerity (diroximel 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:Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone, Generic glatiramer acetate, Glatopa, Kesimpta*, Mayzent, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
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 20 MG/ML	6240003010E520	Brand
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
AUBAGIO	TERIFLUNOMIDE TAB 7 MG	62404070000320	Brand
AUBAGIO	TERIFLUNOMIDE TAB 14 MG	62404070000330	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
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 - Prescribed by or in consultation with a neurologist

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:Aubagio, Vumerity	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
AUBAGIO	TERIFLUNOMIDE TAB 7 MG	62404070000320	Brand
AUBAGIO	TERIFLUNOMIDE TAB 14 MG	62404070000330	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DR STARTER BOTTLE 231 MG	62405530006520	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DELAYED RELEASE 231 MG	62405530006540	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 - Prescribed by or in consultation with a neurologist

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 Failure after a trial of at least 4 weeks, 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)
- Glatopa (glatiramer acetate)
- Kesimpta (ofatumumab)
- Dimethyl fumarate

AND

3 - Prescribed by or in consultation with a neurologist

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 - 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 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 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, 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)
- Glatopa (glatiramer acetate)
- Dimethyl fumarate

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone, Extavia, Generic glatiramer acetate, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, 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 20 MG/ML	6240003010E520	Brand
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	PONESIMOD TAB STARTER PACK 2,3,4,5,6,7,8,9 &10 MG	6240706000B720	Brand

STARTER PACK			
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
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 - 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 Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Kesimpta (ofatumumab)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

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

AND

4 - Prescribed by or in consultation with a neurologist

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

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 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

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

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Mavenclad	
Approval Length	1 month(s)
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 Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Kesimpta (ofatumumab)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

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

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Mavenclad	
Approval Length	1 month(s)
Guideline Type	Non Formulary

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 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

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

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Ocrevus	
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

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 Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Kesimpta (ofatumumab)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS

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:Ocrevus	
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

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 - 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:Ocrevus	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS	OCRELIZUMAB SOLN FOR IV INFUSION 300 MG/10ML	62405060002020	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 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Glatopa, generic glatiramer acetate)

- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

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

AND

3 - Not used in combination with another disease-modifying therapy for MS

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:Ocrevus	
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

Approval Criteria

1 - Diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS

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:Ocrevus	
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

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 - 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:Ocrevus	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
OCREVUS	OCRELIZUMAB SOLN FOR IV INFUSION 300 MG/10ML	62405060002020	Brand

Approval Criteria

1 - Diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS

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

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. [13]
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. [19]

4 . References

1. Avonex Prescribing Information. Biogen Inc. Cambridge, MA. March 2020.
2. Betaseron Prescribing Information. Bayer. Whippany, NJ. October 2020.
3. Copaxone Prescribing Information. Teva Pharmaceuticals. North Wales, PA. July 2020.
4. Extavia Prescribing Information. Novartis. East Hanover, NJ. October 2020.
5. Rebif Prescribing Information. Serono Inc. Rockland, MA. October 2020.
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 March 29, 2019.
8. Per clinical consultation with MS specialist, December 29, 2010.
9. Plegridy Prescribing Information. Biogen Idec Inc. Cambridge, MA. January 2021.

10. Aubagio Prescribing Information. Genzyme Corporation. Cambridge, MA. November 2020.
11. Lemtrada Prescribing Information. Genzyme Corporation. Cambridge, MA. September 2020.
12. Glatopa Prescribing Information. Sandoz Inc. Princeton, NJ. January 2020.
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. December 2020.
15. Mayzent Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. January 2021.
16. Mavenclad Prescribing Information. EMD Serono, Inc. Rockland, MA. April 2019.
17. Vumerity Prescribing Information. Biogen Inc. Cambridge, MA. January 2021.
18. Bafiertam Prescribing Information. Banner Life Sciences. High Point, NC. April 2020.
19. Kesimpta Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2020.
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. March 2021.

5 . Revision History

Date	Notes
2/10/2025	Quartz EHB copied to mirrow Optum EHB

Nexavar (sorafenib)

Prior Authorization Guideline

Guideline ID	GL-173199
Guideline Name	Nexavar (sorafenib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/17/2025
P&T Approval Date:	4/4/2006
P&T Revision Date:	5/16/2024

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.

5 . Revision History

Date	Notes
2/17/2025	Quartz EHB GL copied to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-244324
Guideline Name	Ninlaro (ixazomib citrate)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	1/27/2016
P&T Revision Date:	3/19/2025

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. July 2024.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed 12 February, 2024

4 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163559
Guideline Name	Nityr and Orfadin
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 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.

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 chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-163417
Guideline Name	Non-Formulary & Excluded Drug Exceptions Process for Drugs of Clinical Concern
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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-163429
Guideline Name	Non-formulary Descovy and Truvada
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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-278235
Guideline Name	Non-steroidal Anti-Inflammatory Agents - PA, ST
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	11/18/2008
P&T Revision Date:	4/16/2025

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: 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: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
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, indomethacin is not recommended for patients greater than or equal to 65 years old [B] **Per the American Geriatrics Society 2023 updated Beers criteria, chronic use of NSAIDs, including diclofenac, is not recommended for patients greater than or equal to 65 years old unless other 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. November 2024.
2. Pennsaid prescribing information. Horizon Therapeutics USA, Inc. Lake Forest, IL. November 2024.
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. Cambia prescribing information. Assertio Therapeutics, INC. Lake Forest, IL. November 2024.
6. Vivlodex prescribing information. Egalet US Inc. Wayne PA. April 2021.
7. Indocin prescribing information. Zyla Life Sciences, LLC. Wayne, PA. November 2024.
8. Zorvolex prescribing information. Zyla Life Sciences US Inc. Wayne, PA. April 2021.
9. Lofena Prescribing Information. Carwin Pharmaceutical Associates, LLC. Hazlet, NJ. July 2021.
10. Diclofenac Sodium Solution Prescribing Information. Apotex Corporation. Weston, FL. August 2024.
11. Meloxicam Oral Suspension Prescribing Information. Avondale Pharmaceuticals, LLC. Birmingham, AL. January 2024.
12. Indomethacin Suspension Prescribing Information. Zyla Life Sciences, LLC. Wayne, PA. January 2024. November 2024.
13. Tolectin prescribing information. Poly Pharmaceuticals, Inc, Owens Cross Roads, AL 35763. February 2024.
14. Fenopron Prescribing Information. Galt Pharmaceuticals, LLC. Atlanta, GA. September 2024.
15. Zipsor Prescribing Information. Assertio Therapeutics, Inc. Newark, CA. November 2024
16. Dolobid Prescribing Information. INA Pharmaceuticals, INC. June 2024.
17. Celebrex Prescribing Information. Pfizer Laboratories, INC. NY,NY April 2021.

5 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-244325
Guideline Name	Nplate (romiplostim)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	4/7/2009
P&T Revision Date:	2/20/2025

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 January 8 2025.
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 January 9, 2025.

5 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Nucala (mepolizumab)

Prior Authorization Guideline

Guideline ID	GL-163546
Guideline Name	Nucala (mepolizumab)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

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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.
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8. ClinicalTrials.gov Web site. https://clinicaltrials.gov/ct2/show/NCT03085797. Accessed August 15, 2021.
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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-163534
Guideline Name	Octreotide Products - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 changes to criteria.

Ogsiveo (nirogacestat)

Prior Authorization Guideline

Guideline ID	GL-244326
Guideline Name	Ogsiveo (nirogacestat)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/15/2024
P&T Revision Date:	2/20/2025

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
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163556
Guideline Name	Omega-3-Acid Derivatives
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

A. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [3]

5 . References

1. Lovaza prescribing information. GlaxoSmithKline. Research Triangle Park, NC. February 2021.
2. Vascepa prescribing information. Amarin Pharma Inc. Bedminster, NJ. April 2023.
3. Icosapent ethyl prescribing information. Teva Pharmaceuticals. Parsippany, NJ. August 2021.
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. 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.

Prior Authorization Guideline

Guideline ID	GL-244328
Guideline Name	Oncology Injectable
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	12/19/2018
P&T Revision Date:	3/19/2025

1 . Criteria

Product Name:Adcetris, Aliqopa, Arzerra, Bavencio, Beleodaq, Besponsa, Bizengri, Blincyto, Columvi, Cyramza, Danyelza, Datroway, 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
DATROWAY	DATOPOTAMAB DERUXTECAN-DLNK FOR IV SOLN 100 MG	21551020202120	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
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278236
Guideline Name	Onpattro (patisiran) & Tegsedi (inotersen)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	10/17/2018
P&T Revision Date:	4/16/2025

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

1. Onpattro Prescribing Information. Alnylam Pharmaceuticals, Inc. Cambridge, MA. January 2023.
2. 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.
3. Tegsedi Prescribing Information. Akcea Therapeutics, Inc. Boston, MA. June 2022.
4. 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
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163430
Guideline Name	Onureg (azacitidine)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. Onureg prescribing information. Celgene Corporation. Summt, NJ. October 2022.
2. 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-165061
Guideline Name	Ophthalmic Antihistamines
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/12/2025
P&T Approval Date:	11/16/2010
P&T Revision Date:	9/18/2024

1 . Indications

Drug Name: LASTACAFT (alcaftadine)
Allergic Conjunctivitis Indicated for the prevention of itching associated with allergic conjunctivitis.
Drug Name: ZERVIATE (cetirizine)
Allergic Conjunctivitis Indicated for the treatment of ocular itching associated with allergic conjunctivitis.

2 . Criteria

Product Name:Lastacaft, Zerviate	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
LASTACAFT	ALCAFTADINE OPHTH SOLN 0.25%	86802004002020	Brand
ZERVIATE	CETIRIZINE HCL OPHTH SOLN 0.24% (BASE EQUIV)	86802009102020	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 generics or preferred brands:

- azelastine
- olopatadine

3 . References

1. Lastacaft Prescribing Information. Allergan, Inc, Irvine, CA. June 2020.
2. Zerviate Prescribing Information. Eyevance Pharmaceuticals, Lakewood, NJ. October 2023.

4 . Revision History

Date	Notes
2/12/2025	Quartz EHB copied to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-163420
Guideline Name	Opioid Quantity Limit Overrides
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-163421
Guideline Name	Opioid Risk Management
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 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	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	659910020503 15	Generic
TYLENOL/CODEINE #3	ACETAMINOPHEN W/ CODEINE TAB 300-30 MG	659910020503 15	Brand
ACETAMINOPHEN/CODEINE	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	659910020503 20	Generic
ACETAMINOPHEN/CODEINE PHOSPHATE	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	659910020503 20	Generic
CODEINE/ACETAMINOPHEN	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	659910020503 20	Generic
TYLENOL/CODEINE #4	ACETAMINOPHEN W/ CODEINE TAB 300-60 MG	659910020503 20	Brand
ACETAMINOPHEN/CAFFEINE/DIHYDROCODEINE	ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG	659913030501 15	Generic
TREZIX	ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG	659913030501 15	Generic
HYDROCODONE/IBUPROFEN	HYDROCODONE-IBUPROFEN TAB 7.5-200 MG	659917025003 20	Generic
ULTRAM	TRAMADOL HCL TAB 50 MG	651000951003 20	Brand
TRAMADOL HCL	TRAMADOL HCL TAB 50 MG	651000951003 20	Generic
TRAMADOL HYDROCHLORIDE/ACETAMINOPHEN	TRAMADOL-ACETAMINOPHEN TAB 37.5-325 MG	659950022003 20	Generic
ULTRACET	TRAMADOL-ACETAMINOPHEN TAB 37.5-325 MG	659950022003 20	Brand
BUTORPHANOL TARTRATE	BUTORPHANOL TARTRATE NASAL SOLN 10 MG/ML	652000201020 50	Generic
NALOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	659900022003 03	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A5 40	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A5 60	Brand
OXYCODONE/ASPIRIN	OXYCODONE-ASPIRIN TAB 4.8355-325 MG	659900022203 40	Generic
TUXARIN ER	CODEINE PHOS-CHLORPHENIRAMINE MALEATE TAB ER 12HR 54.3-8 MG	439952023274 30	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, 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. If the prescriber is unable to certify written documentation to meet criterion (2) and/or (3), written or verbal attestation from the provider may be accepted confirming that the prescriber (or prescriber's representative) 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 METHYLBROM SOLN 5-1.5 MG/5ML	43101010102010	Generic
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 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: 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 cri teria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/stren gth combination up to the requested quantity and/or MME for transitio n 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

1. 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-162298
Guideline Name	Orencia (abatacept)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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 section 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 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 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

1. Orencia prescribing information. Bristol-Myers Squibb Company. Princeton, NJ. 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.

5 . Revision History

Date	Notes
12/20/2024	New program

Prior Authorization Guideline

Guideline ID	GL-244331
Guideline Name	Orgovyx (relugolix)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/18/2021
P&T Revision Date:	2/20/2025

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

1. Orgovyx Prescribing Information. Myovant Sciences, Inc. Brisbane, CA. October 2024.

4 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Orserdu (elacestrant)

Prior Authorization Guideline

Guideline ID	GL-278237
Guideline Name	Orserdu (elacestrant)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	4/19/2023
P&T Revision Date:	4/16/2025

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

A. 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

1. Orserdu Prescribing Information. Stemline Therapeutics, Inc., New York, NY. January 2023.
2. 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.
3. Clinical Consult with an oncologist. March 16, 2023.

4. 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
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-249307
Guideline Name	PCSK9 Inhibitors - PA, ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025

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), Secondary Prevention of Cardiovascular Events in Patients with ASCVD
Approval Length	When approved; no reauthorization required
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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

Product Name:Praluent (F)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH)], Atherosclerotic Cardiovascular Disease (ASCVD), Secondary Prevention of Cardiovascular Events in Patients with ASCVD
Approval Length	When approved; no reauthorization required
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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

Product Name:Praluent (NF)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH)], Atherosclerotic Cardiovascular Disease (ASCVD), 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), 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	When approved; no reauthorization required
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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

Product Name:Praluent (F)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	When approved; no reauthorization required
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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

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

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. [3]

4 . References

1. Praluent Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. March 2024.
2. Repatha Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2025.
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 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
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5 . Revision History

Date	Notes
5/1/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx/EHB

Prior Authorization Guideline

Guideline ID	GL-163431
Guideline Name	Prior Authorization Administrative Guideline
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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-244333
Guideline Name	Promacta (eltrombopag)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/17/2009
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Promacta (eltrombopag)
Treatment of Thrombocytopenia in Patients with Persistent or Chronic Immune Thrombocytopenia (ITP) Indicated for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune 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 Chronic 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.

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.

Limitations of Use PROMACTA 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:Promacta	
Diagnosis	Persistent or Chronic Immune Thrombocytopenia (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 Immune Thrombocytopenia (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

A. The prescribing information states that the total duration of Promacta treatment for first-line severe aplastic anemia is 6 months. [1]
B. 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]
C. 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

1. Promacta Prescribing Information. Novartis Pharmaceuticals Corp. East Hanover, NJ. March 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 January 15, 2021.
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. Promacta product dossier. GlaxoSmithKline. Research Triangle Park, NC. 2013.
6. 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.
7. Marsh JC, Ball SE, Cavenagh J, et al. Guidelines for the diagnosis and management of aplastic anemia. Br J Haematol. 2009;147(1):43-70.
8. Per clinical consult with hematologist/oncologist. June 20, 2018.
9. 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.
10. Per clinical consult with hematologist/oncologist. January 24, 2019.

5 . Revision History

Date	Notes
4/28/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163958
Guideline Name	Proton Pump Inhibitors
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

A. 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

1. Aciphex Prescribing Information. Eisai Inc. Woodcliff Lake, NJ. November 2020.
2. Aciphex Sprinkle Prescribing Information. Cerecor, Inc. Rockville, MD June 2018.
3. Esomeprazole Strontium Prescribing Information. Amneal Pharmaceuticals LLC. Glasgow, KY. January 2021.
4. Prilosec Prescribing Information. AstraZeneca Pharmaceuticals LP. wilmington, DE. March 2024.
5. Protonix Prescribing Information. Wyeth Pharmaceuticals, Inc. Philadelphia, PA. June 2023.
6. Zegerid Prescribing Information. Salix Pharmaceuticals. Bridgewater, NJ. July 2023.
7. Dexilant Prescribing Information. Takeda Pharmaceuticals America, Inc. Deerfield, IL. July 2023.
8. Nexium Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. July 2023.
9. Prevacid Prescribing Information. Takeda Pharmaceuticals, Inc. Deerfield, IL. August 2023.

10. First-Omeprazole Prescribing Information. Azurity Pharmaceuticals. Wilmington, MA. July 2020.
11. First-Lansoprazole Prescribing Information. Azurity Pharmaceuticals. Wilmington, MA. August 2020.
12. Micromedex solutions Web site. http://www.micromedexsolutions.com/home/dispatch. Accessed August 19, 2020.
13. 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.
14. 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.
15. 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.
16. 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-163422
Guideline Name	Provigil (modafinil), Nuvigil (armodafinil)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

A. 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]
B. 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].
C. Examples of obstructive respiratory events include: obstructive and mixed apneas, hypopneas, or respiratory effort related arousals (RERA) [6].
D. 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].
E. 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]
F. 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]
G. 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]

5 . References

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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-249310
Guideline Name	Pulmonary Arterial Hypertension Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025

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	When approved; no reauthorization required

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
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
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve through 12/31/2039

Product Name:Brand Adcirca tablet, Tadliq oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

Product Name:Brand Letairis tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve through 12/31/2039

Product Name:Opsynvi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

3 - 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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

Product Name:Brand Remodulin injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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	
Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

Product Name:Brand Revatio tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve through 12/31/2039

Product Name:Brand Tracleer tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve through 12/31/2039

Product Name:Brand Revatio injection or Generic sildenafil injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

Product Name:Liqrev, Brand Revatio oral suspension or Generic sildenafil oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

Product Name:Adempas tablet	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039

	For reauthorization request, bypass criteria review and approve through 12/31/2039

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	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

Product Name:Uptravi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve through 12/31/2039

Product Name:Uptravi injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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]

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve throu gh 12/31/2039

Product Name:Winrevair Injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For reauthorization request, bypass criteria review and approve through 12/31/2039 For reauthorization request, bypass criteria review and approve through 12/31/2039

3 . Endnotes

A. 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

1. Flolan Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. October 2023.
2. Revatio Prescribing Information. Viatris Specialty LLC. Morgantown, WV. January 2023.
3. Ventavis Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. March 2022.

4. Tyvaso Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. May 2022.
5. Remodulin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. October 2023.
6. Adcirca Prescribing Information. Eli Lilly and Company. Indianapolis, IN. September 2020.
7. Letairis Prescribing Information. Gilead Sciences, Inc. Foster City, CA. August 2019.
8. Tracleer Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
9. Veletri Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
10. Opsumit Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. June 2023.
11. Adempas Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. September 2021.
12. Orenitram Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. August 2023.
13. Uptravi Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
14. Alyq Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. September 2021.
15. Tyvaso DPI Prescribing Information. United Therapeutics Corporation. Research Triangle Park, NC. June 2023.
16. Tadliq Prescribing Information. CMP Pharma, Inc. Farmville, NC. October 2023.
17. Liqrev Prescribing Information. CMP Pharma, Inc. Farmville, NC. April 2023.
18. Winrevair Prescribing Information. Merck Sharp & Dohme LLC. March 2023
19. Opsynvi Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. April 2024.

5 . Revision History

Date	Notes
5/1/2025	Quartz Comm/EHB guideline copied to mirrow OptumRx/EHB

Prior Authorization Guideline

Guideline ID	GL-231286
Guideline Name	Pyrukynd (mitapivat)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	4/2/2025

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

A. 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]
B. In case of decreased PK activity, sequencing of PKLR gene is highly recommended to confirm the diagnosis [2]
C. 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

1. Pyrukynd (mitapivat) [prescribing information]. Agios Pharmaceuticals, Inc. Cambridge, MA. February 2022.
2. 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.
3. 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.
4. UpToDate Pyruvate Kinase Deficiency. Available at https://www.uptodate.com/contents/pyruvate-kinase-deficiency. Accessed April 1, 2024.
5. 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.
6. Clinical consult April 8, 2022.
7. May P & T Committe feedback. May 19, 2022.

8. 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.

5 . Revision History

Date	Notes
4/2/2025	Copied from Quartz Comm to Quartz EHB

Prior Authorization Guideline

Guideline ID	GL-278238
Guideline Name	Quantity Limit General
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	5/20/2008
P&T Revision Date:	4/16/2025

Note:

For all other drugs subject to quantity limits, OptumRx may authorize coverage for additional quantities of medications listed on the Standard QL list for patients who meet the following criteria.

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
5/22/2025	Quartz guideline copied to mirrow OptumRx

Reblozyl (luspatercept-aamt)

Prior Authorization Guideline

Guideline ID	GL-250190
Guideline Name	Reblozyl (luspatercept-aamt)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	3/1/2021
P&T Revision Date:	2/20/2025

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

1. Reblozyl Prescribing Information. Celgene Corporation. Summit, NJ. May 2024.
2. 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.
3. Per clinical consult with oncologist, December 19, 2019.
4. 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
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-285191
Guideline Name	Repository Corticotropin Gel Products - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	5/19/2009
P&T Revision Date:	4/16/2025

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 80 UNIT/ML	3030001000D130	Brand
CORTROPHIN	CORTICOTROPIN SUBCUTANEOUS GEL PREFILLED SYR 40 UNIT/0.5ML	3030001000E420	Brand
CORTROPHIN	CORTICOTROPIN SUBCUTANEOUS GEL PREFILLED SYRINGE 80 UNIT/ML	3030001000E430	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 one high dose corticosteroid treatment (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 80 UNIT/ML	3030001000D130	Brand
CORTROPHIN	CORTICOTROPIN SUBCUTANEOUS GEL PREFILLED SYR 40 UNIT/0.5ML	3030001000E420	Brand
CORTROPHIN	CORTICOTROPIN SUBCUTANEOUS GEL PREFILLED SYRINGE 80 UNIT/ML	3030001000E430	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 u se 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, Purified Cortrophin Gel	
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 80 UNIT/ML	3030001000D130	Brand
CORTROPHIN	CORTICOTROPIN SUBCUTANEOUS GEL PREFILLED SYR 40 UNIT/0.5ML	3030001000E420	Brand
CORTROPHIN	CORTICOTROPIN SUBCUTANEOUS GEL PREFILLED SYRINGE 80 UNIT/ML	3030001000E430	Brand
CORTROPHIN	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
ACTHAR	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	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 one high dose corticosteroid treatment (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	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 80 UNIT/ML	3030001000D130	Brand
CORTROPHIN	CORTICOTROPIN SUBCUTANEOUS GEL PREFILLED SYR 40 UNIT/0.5ML	3030001000E420	Brand
CORTROPHIN	CORTICOTROPIN SUBCUTANEOUS GEL PREFILLED SYRINGE 80 UNIT/ML	3030001000E430	Brand
CORTROPHIN	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
ACTHAR	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	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

A. 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

1. Acthar prescribing information. Mallinckrodt ARD LLC. Bedminster, NJ. June 2024.
2. 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.
3. 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.
4. Thompson, AJ. Relative efficacy of IV methylprednisolone vs ACTH in acute relapse of MS. Neurology. 1989 July;39(7):969.
5. 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.

6. 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.
7. Brown, A. Repository corticotropin injection in patients with refractory psoriatic arthritis: a case series. Open Access Rheumatol. 2016;8:97-102.
8. 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.
9. Patel A, Seely G, Aggarwal R. Repository corticotropin injection for treatment of idiopathic inflammatory myopathies. Case Rep Rheumatol. 2016;2016:9068061.
10. 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.
11. Baughman RP, Sweiss N, Keijsers R, et al. Repository corticotropin for chronic pulmonary sarcoidosis. Lung. 2017;195(3):313-322.
12. 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.
13. 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.
14. Sharon Y, Chu DS. Adrenocorticotropic hormone gel for patients with non-infectious uveitis. Am J Ophthalmol Case Rep. 2019;15:100502.
15. 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.
16. Purified Cortrophin Gel prescribing information. ANI Pharmaceuticals, Inc. Baudette, MN. October 2023.

5 . Revision History

Date	Notes
5/29/2025	Quartz guideline copied to mirrow OptumRx

Restasis (cyclosporine 0.05%)

Prior Authorization Guideline

Guideline ID	GL-165062
Guideline Name	Restasis (cyclosporine 0.05%)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/12/2025

1 . Indications

Drug Name: Restasis (cyclosporine 0.05%) ophthalmic emulsion
Keratoconjunctivitis sicca Indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

2 . Criteria

Product Name:Brand Restasis, Generic cyclosporine 0.05% ophthalmic emulsion	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RESTASIS	CYCLOSPORINE (OPHTH) EMULSION 0.05%	86720020001620	Brand
RESTASIS MULTIDOSE	CYCLOSPORINE (OPHTH) EMULSION 0.05%	86720020001620	Brand
CYCLOSPORINE	CYCLOSPORINE (OPHTH) EMULSION 0.05%	86720020001620	Generic

Approval Criteria

1 - One of the following:

1.1 Diagnosis of moderate to severe keratoconjunctivitis sicca (dry eye)

OR

1.2 Diagnosis of Sjogren syndrome with suppressed tear production due to ocular inflammation

AND

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

2.1 Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

OR

2.2 Topical ophthalmic anti-inflammatory drugs will only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with the requested drug

Product Name:Brand Restasis, generic cyclosporine 0.05% ophthalmic emulsion	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

RESTASIS	CYCLOSPORINE (OPHTH) EMULSION 0.05%	86720020001620	Brand
RESTASIS MULTIDOSE	CYCLOSPORINE (OPHTH) EMULSION 0.05%	86720020001620	Brand
CYCLOSPORINE	CYCLOSPORINE (OPHTH) EMULSION 0.05%	86720020001620	Generic

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

AND

2 - Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

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). 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]
B. The FDA-approved indication states that during clinical trials, increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs. [1]

4 . References

1. Restasis Prescribing Information. Allergan Inc. Irvine, CA. July 2017.
2. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Committee. Dry Eye Syndrome PPP - 2018. November 2018. https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018. Accessed May 28, 2021.

5 . Revision History

Date	Notes
2/12/2025	Quartz EHB copied to mirrow Optum EHB

Retevmo (selpercatinib)

Prior Authorization Guideline

Guideline ID	GL-163550
Guideline Name	Retevmo (selpercatinib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

A. 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

1. 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 changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-250191
Guideline Name	Revcovi (elapegademase-lvlr)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	1/16/2019
P&T Revision Date:	2/20/2025

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

1. Revcovi Prescribing Information. Chiesi USA, Inc. Cary, NC 27518. August 2022
2. Immune Deficiency Foundation Patient & Family Handbook for Primary Immunodeficiency Diseases. Fifth Edition. 2013.

4 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Revlimid (lenalidomide)

Prior Authorization Guideline

Guideline ID	GL-278239
Guideline Name	Revlimid (lenalidomide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	6/6/2006
P&T Revision Date:	4/16/2025

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

A. 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

1. Revlimid Prescribing Information. Celgene Corporation. Princeton, NJ. March 2023.
2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available by subscription at: www.nccn.org. Accessed March 24, 2025.

5 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278241
Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	7/26/2017
P&T Revision Date:	4/16/2025

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

A. 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.
B. 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.
C. An FDA-approved biosimilar is an appropriate substitute for rituximab. [3]
D. 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. Rixtuan Hycela Prescribing Information. Genentech, Inc. South San Francisco, CA. June 2021.
2. 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.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 25, 2024.
4. 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
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-160454
Guideline Name	Rituximab - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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 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	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 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: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 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 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

A. 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.

B. 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]
C. 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]
D. An FDA-approved biosimilar is an appropriate substitute for rituximab. [23, 25]

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6 . Revision History

Date	Notes
11/11/2024	Bulk copying over Quartz Comm guidelines to Quartz EHB

Prior Authorization Guideline

Guideline ID	GL-250192
Guideline Name	Rydapt (midostaurin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	6/28/2017
P&T Revision Date:	2/20/2025

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

A. 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

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5 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Sabril, Vigadrone, Vigafyde, Vigpoder (vigabatrin)

Prior Authorization Guideline

Guideline ID	GL-250193
Guideline Name	Sabril, Vigadrone, Vigafyde, Vigpoder (vigabatrin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	
P&T Revision Date:	3/19/2025

1 . Indications

Drug Name: Sabril (vigabatrin), Vigadrone (vigabatrin), Vigpoder (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, Vigpoder	
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
VIGPODER	VIGABATRIN POWD PACK 500 MG	72170085003020	Generic

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, Vigpoder	
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
VIGPODER	VIGABATRIN POWD PACK 500 MG	72170085003020	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. 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]

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

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5. Vigafyde Prescribing Information. Pyros Pharmaceuticals, Inc. Parsippany, NJ. June 2024.
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5 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163557
Guideline Name	Sapropterin Products
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

A. All patients who are treating phenylketonuria (PKU) with sapropterin should also be treated with a phenylalanine (Phe) restricted diet [1].
B. 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).
C. 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.
D. 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.

E. Phe blood levels should be checked after one week of sapropterin treatment and periodically after that to assess blood Phe control [1].

4 . References

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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-165064
Guideline Name	Savella
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/12/2025
P&T Approval Date:	
P&T Revision Date:	3/20/2024

1 . Indications

Drug Name: Savella (milnacipran)
Fibromyalgia Indicated for the management of fibromyalgia. Savella is not approved for use in pediatric patients.

2 . Criteria

Product Name:Savella, Savella Titration Pack	
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

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 generics: [A]

- amitriptyline*
- cyclobenzaprine*
- duloxetine
- gabapentin
- pregabalin

Notes	*Amitriptyline and cyclobenzaprine are considered to be potentially inappropriate medications for use in patients 65 years of age and older. [2, A]

3 . Endnotes

A. The 2019 Beers Criteria recommends avoiding the use of amitriptyline (independent of diagnosis or condition) and cyclobenzaprine in older adults due to their highly anticholinergic and sedating properties. [2] However, amitriptyline and cyclobenzaprine have strong evidence for efficacy in treating fibromyalgia. [3]

4 . References

1. Savella Prescribing Information. Allergan USA, Inc. Irvine, CA. September 2021.
2. American Geriatrics Society. American Geriatrics Society 2019 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2019 Jan 29.
3. Clauw DJ. Fibromyalgia: a clinical review. JAMA. 2014 Apr 16;311(15):1547-55.

5 . Revision History

Date	Notes
2/12/2025	Quartz EHB copied to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-244283
Guideline Name	Savella (milnacipran)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	
P&T Revision Date:	3/19/2025

1 . Indications

Drug Name: Savella (milnacipran)
Fibromyalgia Indicated for the management of fibromyalgia. Savella is not approved for use in pediatric patients.

2 . Criteria

Product Name:Savella, Savella Titration Pack	
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

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: [A]

- amitriptyline*
- cyclobenzaprine*
- duloxetine
- gabapentin
- pregabalin

Notes	*Amitriptyline and cyclobenzaprine are considered to be potentially inappropriate medications for use in patients 65 years of age and older. [2, A]

3 . Endnotes

A. The 2019 Beers Criteria recommends avoiding the use of amitriptyline (independent of diagnosis or condition) and cyclobenzaprine in older adults due to their highly anticholinergic and sedating properties. [2] However, amitriptyline and cyclobenzaprine have strong evidence for efficacy in treating fibromyalgia. [3]

4 . References

1. Savella Prescribing Information. Allergan USA, Inc. Irvine, CA. May 2024.
2. American Geriatrics Society. American Geriatrics Society 2019 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2019 Jan 29.
3. Clauw DJ. Fibromyalgia: a clinical review. JAMA. 2014 Apr 16;311(15):1547-55.

5 . Revision History

Date	Notes
4/25/2025	Quartz EHB guideline copied to mirrow OptumRx -EHB

Selzentry (maraviroc)

Prior Authorization Guideline

Guideline ID	GL-163423
Guideline Name	Selzentry (maraviroc)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. Selzentry Prescribing Information. ViiV Healthcare. Durham, NC. September 2022.
2. 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-250194
Guideline Name	SGLT2 Inhibitors - ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	7/9/2013
P&T Revision Date:	2/20/2025

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: 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
Drug Name: Invokana (canagliflozin)

Type 2 Diabetes 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. 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 patients 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: Invokamet (canagliflozin/metformin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years and older aged with type 2 diabetes mellitus. Canagliflozin, when used as a component of INVOKAMET, is indicated in adults with type 2 diabetes mellitus to reduce the risk of: 1) Major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). 2) 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 and pediatric patients aged 10 years and older with type 2 diabetes mellitus. Canagliflozin, when used as a component of INVOKAMET XR, is indicated in adults with type 2 diabetes mellitus to reduce the risk of: 1) Major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). 2) 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: 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.

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

1. Invokana Prescribing Information. Janssen. Titusville, NJ. December 2024.
2. Invokamet Prescribing Information. Janssen. Titusville, NJ. December 2024.
3. Invokamet XR Prescribing information. Janssen Ortho, LLC. Titusville, NJ. December 2024.
4. Qtern Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. November 2024.
5. Segluromet Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. December 2024.
6. Steglatro Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. December 2024.
7. Steglujan Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. December 2024.
8. 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.
9. 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.
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.
11. Brenzavvy Prescribing Information. TheracosBio, LLC. Marlborough, MA. February 2024.
12. Inpefa Prescribing Information. Lexicon Pharmaceuticals, Inc. The Woodlands, TX. January 2024.

4 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163399
Guideline Name	Signifor, Signifor LAR (pasireotide) - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. Signifor LAR Prescribing Information. Recordati Rare Diseases Inc. Bridgewater, NJ. July 2024.
2. 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-163432
Guideline Name	Simponi, Simponi Aria (golimumab)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. Simponi Prescribing Information. Janssen Biotech Inc. Horsham, PA. September 2019.
2. Simponi Aria Prescribing Information. Janssen Biotech, Inc. Horsham, PA. February 2021.
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. 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.
5. 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.
6. 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.
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. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
9. 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 chang es to criteria.

Prior Authorization Guideline

Guideline ID	GL-165065
Guideline Name	Skin Cancer Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/12/2025
P&T Approval Date:	4/10/2012
P&T Revision Date:	4/17/2024

1 . Indications

Drug Name: diclofenac sodium gel 3%
Actinic keratosis Indicated for the topical treatment of actinic keratoses. Sun avoidance is indicated during therapy.

2 . Criteria

Product Name:diclofenac sodium 3% gel	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
DICLOFENAC SODIUM	DICLOFENAC SODIUM (ACTINIC KERATOSES) GEL 3%	90374035304020	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 generics:

- imiquimod
- fluorouracil

3 . References

1. American Academy of Dermatology. Actinic Keratosis: diagnosis and treatment. https://www.aad.org/public/diseases/scaly-skin/actinic-keratosis#treatment. Accessed March 25, 2024.
2. Diclofenac sodium gel 3% Prescribing Information. Fort Collins, CO: Tolmar Inc.; June 2021.

4 . Revision History

Date	Notes
2/12/2025	Quartz EHB copied to mirrow Optum EHB

Skyclarys (omaveloxolone)

Prior Authorization Guideline

Guideline ID	GL-220219
Guideline Name	Skyclarys (omaveloxolone)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	5/18/2023
P&T Revision Date:	1/15/2025

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 B-type natriuretic peptide value less than or equal to 200 pg/mL

AND

4 - 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

3 . References

1. Skyclarys Prescribing Information. Reata Pharmaceuticals, Inc. Cambridge, MA. January 2024.

4 . Revision History

Date	Notes
3/18/2025	Quartz guideline copied to mirrow Optum standard and EHB

Prior Authorization Guideline

Guideline ID	GL-260211
Guideline Name	Soliris (eculizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	11/19/2014
P&T Revision Date:	2/20/2025

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 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

4 - 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

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

3 . References

1. Soliris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. September 2024.
2. 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.
3. 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
5/13/2025	Quartz guideline updated to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-249211
Guideline Name	Somatuline Depot (lanreotide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	11/13/2007
P&T Revision Date:	2/20/2025

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

AND

4 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

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

AND

2 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

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

AND

3 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

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

AND

2 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

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

AND

4 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

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

AND

2 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

3 . References

1. Somatuline Depot Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. July 2024.
2. Lanreotide Injection Prescribing Information. Cipla USA Inc. Warren, NJ. July 2024.

4 . Revision History

Date	Notes
4/30/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163424
Guideline Name	Somavert (pegvisomant)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. Somavert Prescribing Information. Pharmacia & Upjohn Company LLC. New York, NY. July 2023.

2. 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.

Prior Authorization Guideline

Guideline ID	GL-207284
Guideline Name	Spevigo (spesolimab-sbzo)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	
P&T Revision Date:	12/18/2024

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 (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

A. 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].
B. The total Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score ranges from 0 (clear) to 4 (severe) [1].

4 . References

1. Spevigo Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. March 2024.
2. 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.
3. Armstrong AW, Elston CA, Elewski BE, Ferris LK, Gottlieb AB, Lebwohl MG; Medical Board of the National Psoriasis Foundation. Generalized pustular psoriasis: A consensus statement from the National Psoriasis Foundation. J Am Acad Dermatol. 2024 Apr;90(4):727-730. doi: 10.1016/j.jaad.2023.09.080. Epub 2023 Oct 13.

5 . Revision History

Date	Notes
3/4/2025	Quartz Comm/EHB copied to mirrow Optumrx and EHB

Sprycel (dasatinib)

Prior Authorization Guideline

Guideline ID	GL-249212
Guideline Name	Sprycel (dasatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	10/3/2006
P&T Revision Date:	2/20/2025

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)

3 . References

1. Sprycel [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; July 2024.
2. 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
4/30/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-211188
Guideline Name	State Mandate Reference Document
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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-163552
Guideline Name	Sucraid (sacrosidase) Oral Solution
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. Sucraid Prescribing Information. QOL Medical, LLC. Vero Beach, FL. August 2024.
2. 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.
3. 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.
4. 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.

Prior Authorization Guideline

Guideline ID	GL-250195
Guideline Name	Sutent (sunitinib) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	4/1/2006
P&T Revision Date:	3/19/2025

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

A. 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

1. Sutent Prescribing Information. Pfizer Labs. New York, NY. August 2021.

5 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-158802
Guideline Name	Syfovre (pegcetacoplan)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Syfovre (pegcetacoplan)
Geographic Atrophy (GA) Indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

2 . Criteria

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

Product Name	Generic Name	GPI	Brand/Generic
SYFOVRE	PEGCETACOPLAN INTRAVITREAL SOLN 15 MG/0.1ML (150 MG/ML)	86454065002020	Brand

Approval Criteria

1 - Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) as confirmed by one of the following:

- Fundus photography (e.g. fundus autofluorescence [FAF])
- Optical coherence tomography (OCT)
- Fluorescein angiography

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

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

Product Name	Generic Name	GPI	Brand/Generic
SYFOVRE	PEGCETACOPLAN INTRAVITREAL SOLN 15 MG/0.1ML (150 MG/ML)	86454065002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in growth rate of GA lesion)

3 . References

1. Syfovre Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. November 2023.

Prior Authorization Guideline

Guideline ID	GL-165066
Guideline Name	Tadalafil
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/12/2025
P&T Approval Date:	7/18/2018
P&T Revision Date:	7/17/2024

1 . Indications

Drug Name: Generic tadalafil
Benign Prostatic Hyperplasia (BPH) and Erectile Dysfunction (ED) Indicated for 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 tadalafil is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit of tadalafil beyond 26 weeks is unknown.

2 . Criteria

Product Name:Generic tadalafil 2.5 mg or generic tadalafil 5 mg

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TADALAFIL	TADALAFIL TAB 2.5 MG	40304080000302	Generic
TADALAFIL	TADALAFIL TAB 5 MG	40304080000305	Generic
Cialis			

Approval Criteria

1 - Diagnosis of benign prostatic hyperplasia (BPH)

Notes	Quantity limit: Cialis (tadalafil) 2.5 mg and 5 mg tablets will be subject to a quantity limit of 1 tablet per day.

3 . References

1. Tadalafil Prescribing Information. Ajanta Pharma USA Inc. Bridgewater, NJ. May 2023.

4 . Revision History

Date	Notes
2/12/2025	Quartz EHB copied to mirrow Optum EHB.

Tafinlar (dabrafenib)

Prior Authorization Guideline

Guideline ID	GL-250196
Guideline Name	Tafinlar (dabrafenib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	7/9/2013
P&T Revision Date:	3/19/2025

1 . Indications

Drug Name: Tafinlar (dabrafenib)
Limitations of Use: TAFINLAR is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. TAFINLAR is not indicated for treatment of patients with wild-type BRAF solid tumors. **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. **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.

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.

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.

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.

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.

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.

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

A. 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

1. Tafinlar Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2024.
2. 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
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278243
Guideline Name	Tagrisso (osimertinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	1/27/2016
P&T Revision Date:	4/16/2025

1 . Indications

Drug Name: Tagrisso (osimertinib)
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. **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. **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.

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.

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.

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 Presence of 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 Presence of 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 - Presence of 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 - Presence of 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 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

1. Tagrisso prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. September 2024.
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 19, 2025.
3. National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Non-small cell lung cancer. v.3.2025. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 19, 2025.

4 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278247
Guideline Name	Tarceva (erlotinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	7/14/2003
P&T Revision Date:	4/16/2025

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
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
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 - Presence of 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

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
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
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
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

1. Tarceva Prescribing Information. Genentech USA, Inc. South San Francisco, CA. October 2016.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-small cell lung cancer. v.3.2025. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 24, 2025.
3. Erlotinib Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. January 2019.

4 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278252
Guideline Name	Tasigna (nilotinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	10/3/2006
P&T Revision Date:	5/15/2025

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

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

3 . Endnotes

A. 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

1. Tasigna Prescribing Information. Novartis Pharmaceutical Corporation. East Hanover, NJ. February 2024.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic Myelogenous Leukemia v.3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed March 24, 2025.

5 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-163425
Guideline Name	Tavneos (avacopan) - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. Tavneos Prescribing Information. ChemoCentryx, Inc. San Carlos, CA. October 2021.
2. 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
3. Per clinical consult with rheumatologist November 17, 2021.
4. 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.
5. 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 changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-164953
Guideline Name	Tecfidera (dimethyl fumarate) - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/10/2025
P&T Approval Date:	6/16/2021
P&T Revision Date:	5/19/2022

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: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 - 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 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to both of the following:

- generic dimethyl fumarate
- Bafiertam (monomethyl fumarate) [A, 5]

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: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 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to both of the following:

- generic dimethyl fumarate
- Bafiertam (monomethyl fumarate)

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 - Documentation of 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 [B, 6, 7]

AND

3 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. Although the trial results of Bafiertam was based off of Tecfidera, the consultant thinks that the two drugs should have the same efficacy and safety profile since Bafiertam was approved via the FDA 505(b)(2) pathway. [5]
B. 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

1. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.
2. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed March 29, 2019.
3. Tecfidera Prescribing Information. Biogen Idec Inc. Cambridge, MA. February 2022.
4. Dimethyl Fumarate Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. May 2020.

5. Per clinical consultation with MS specialist, July 22, 2020.
6. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. Mayo Clinic Proceedings, 89(2), 225-240.
7. 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
2/10/2025	Quartz EHB copied to mirrow OptumEHB

Prior Authorization Guideline

Guideline ID	GL-278253
Guideline Name	Tepmetko (tepotinib) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	4/21/2021
P&T Revision Date:	4/16/2025

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

A. 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

1. Tepmetko Prescribing Information. EMD Serono, Inc. Rockland, MA. February 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed March 24, 2025.

5 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-230249
Guideline Name	Teriparatide Products - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/12/2025
P&T Approval Date:	1/3/2003
P&T Revision Date:	06/19/2024 ; 6/19/2024

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 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

Approval Criteria

1 - One of the following diagnosis:

- 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 - One of the following: [7,B]

3.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

3.2 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)

Product Name:Brand 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

Approval Criteria

1 - One of the following: [7,B]

1.1 Treatment duration of parathyroid hormones (e.g., teriparatide) 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)

Product Name:Brand Forteo, 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)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
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 diagnosis:

- 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 Brand Teriparatide

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide) 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)

Product Name:Brand 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

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 - One of the following: [7,B]

5.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

5.2 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)

Product Name:Brand 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

Approval Criteria

1 - One of the following: [7,B]

1.1 Treatment duration of parathyroid hormones (e.g., teriparatide) 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)

Product Name:Brand Forteo, generic teriparatide	
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
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 - 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 Brand Teriparatide

AND

6 - One of the following: [7,B]

6.1 Treatment duration of parathyroid hormones (e.g., teriparatide) 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)

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

A. 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]
B. 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]
C. 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]
D. 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]
E. 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]
F. 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

1. Forteo prescribing information. Eli Lilly and Company. Indianapolis, IN. April 2021.
2. 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.
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6 . Revision History

Date	Notes
3/31/2025	March On-Cycle GPI change

Prior Authorization Guideline

Guideline ID	GL-249213
Guideline Name	Testosterone
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	5/17/2005
P&T Revision Date:	3/19/2025

1 . Indications

Drug Name: 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:Brand Androgel 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
FORTESTA	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Brand
TESTIM	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	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** [5, 6]

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** [5, 6]

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 generic testosterone gel

- Generic testosterone gel

Notes	***This may require treatment to be temporarily held.

Product Name:Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel 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
Approval Length	12 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FORTESTA	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Brand
TESTIM	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	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:Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel 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
FORTESTA	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Brand
TESTIM	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	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 [9-10, 15, 24]

AND

2 - Using hormones to change characteristics to align with gender expression [9, 15, 26-27]

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 [9-10, 15, 24]

AND

2 - Using hormones to change characteristics to align with gender expression [9, 15, 26-27]

Product Name:Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel 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	Gender dysphoria/Gender incongruence

Approval Length	12 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FORTESTA	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Brand
TESTIM	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	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: [27]

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 physiologic male range of 320 to 1000 ng/dL

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 the normal physiologic male range of 320 to 1000 ng/dL 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

A. 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]

B. 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]

C. 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."
D. 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]
E. 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].
F. 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

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5 . Revision History

Date	Notes
4/30/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-160455
Guideline Name	Tocilizumab
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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 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	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
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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
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TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
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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

A. 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]
B. 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

1. Actemra Prescribing Information. Genentech, Inc. South San Francisco, CA. December 2022.
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. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. Tofidence Prescribing Information. Biogen MA Inc. Cambridge, MA. September 2023.
10. Tyenne Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. March 2024.

6 . Revision History

Date	Notes
11/11/2024	Bulk copying over Quartz Comm guidelines to Quartz EHB

Prior Authorization Guideline

Guideline ID	GL-278254
Guideline Name	Tolvaptan Products - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	4/21/2021
P&T Revision Date:	4/16/2025

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

A. 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]

B. 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]
C. 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]
D. 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]
E. 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

1. Samsca Prescribing Information. Otsuka America Pharmaceuticals, Inc. Rockville, MD. April 2021.
2. Ghali JK. Mechanisms, risks, and new treatment options for hyponatremia. Cardiology. 2008;11:147-157.
3. 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.
4. Jynarque Prescribing Information. Otsuka America Pharmaceuticals, Inc. Rockville, MD. October 2020.

5 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-250197
Guideline Name	Topical Antifungals - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/15/2016
P&T Revision Date:	2/20/2025

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
CICLOPIROX NAIL LACQUER	CICLOPIROX SOLUTION 8%	90150030002020	Generic
CICLOPIROX	CICLOPIROX SOLUTION 8%	90150030002020	Generic
CICLODAN	CICLOPIROX SOLUTION 8%	90150030002020	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
CICLOPIROX NAIL LACQUER	CICLOPIROX SOLUTION 8%	90150030002020	Generic
CICLOPIROX	CICLOPIROX SOLUTION 8%	90150030002020	Generic
CICLODAN	CICLOPIROX SOLUTION 8%	90150030002020	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

A. 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]
B. 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

1. Jublia prescribing information. Bausch Health Companies Inc. Bridgewater, NJ. March 2022.
2. Kerydin prescribing information. PharmaDerm, a division of Fougera Pharmaceuticals, Inc. Melville, NY. August 2018.
3. 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.
4. Roberts DT, Taylor WD, Boyle J. Guidelines for treatment of onychomycosis. Br J Dermatol. 2003;148:402-410.
5. 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.
6. 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.

7. Gupta AK, Daigle D, Foley KA. Topical therapy for toenail onychomycosis: an evidence-based review. Am J Clin Dermatol. 2014;15:489.
8. Tavaborole prescribing information. Alembic Pharmaceuticals, Inc. Bridgewater, NJ. November 2021.

5 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-165069
Guideline Name	Topical Retinoid Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/12/2025
P&T Approval Date:	12/16/2005
P&T Revision Date:	7/19/2023

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:Aklief, 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 0.1%	90050030003710	Brand
RETIN-A	TRETINOIN CREAM 0.05%	90050030003705	Brand
RETIN-A	TRETINOIN GEL 0.01%	90050030004005	Brand
RETIN-A	TRETINOIN CREAM 0.025%	90050030003703	Brand
RETIN-A	TRETINOIN GEL 0.025%	90050030004010	Brand
ADAPALENE	ADAPALENE SOLN 0.1%	90050003002010	Brand
ALTRENO	TRETINOIN LOTION 0.05%	90050030004130	Brand
ADAPALENE	ADAPALENE PADS 0.1%	90050003004310	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
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 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: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: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

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 0.1% 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

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
	Alclometasone dipropionate	Cream, ointment	0.05

Low potency	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 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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6 . Revision History

Date	Notes
2/12/2025	Quartz EHB copied to mirrow Optum EHB

Prior Authorization Guideline

Guideline ID	GL-217192
Guideline Name	Trastuzumab - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

A. 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]

B. 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]
C. 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

1. Herceptin Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2021.
2. Herceptin Hylecta Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2019.
3. Kanjinti Prescribing Information. Amgen Inc. Thousand Oaks, CA. October 2019.
4. The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available at www.nccn.org. Accessed May 15, 2023.
5. 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.
6. Ogivri Prescribing Information. Mylan Institutional LLC. Rockford, IL. February 2021.
7. Trazimera Prescribing Information. Pfizer Laboratories Div Pfizer Inc. New York, NY. November 2020.
8. Herzuma Prescribing Information. Celltrion, Inc. Incheon, Republic of Korea. May 2019.
9. Ontruzant Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. March 2020.
10. Hercessi Prescribing Information. Accord BioPharma Inc.Raleigh, NC. September 2024.

5 . Revision History

Date	Notes

3/13/2025	Quartz guideline copied to mirrow OptumRx

Tremfya (guselkumab)

Prior Authorization Guideline

Guideline ID	GL-302229
Guideline Name	Tremfya (guselkumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	9/27/2017
P&T Revision Date:	03/19/2025

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. **Crohn's disease (CD)** Indicated for the treatment of adult patients with moderately to severely active Crohn's disease (CD)

Drug Name: Tremfya IV (guselkumab)
Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis. **Crohn's Disease (CD)** Indicated for the treatment of adult patients with moderately to severely active Crohn's disease (CD)

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	Crohn’s disease (CD)
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 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
- 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:Tremfya SC	
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
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 Crohn's Disease

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - One of the following:

3.1 Will be used as a maintenance dose following the intravenous induction doses

OR

3.2 All of the following:

3.2.1 Will be used for induction dosing

AND

3.2.2 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

3.2.3 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)

Product Name:Tremfya 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
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), Crohn's Disease
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

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

3 . References

1. Tremfya Prescribing Information. Janssen Biotech, Inc. Horsham, PA. September 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. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
6. 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
6/24/2025	Updated guideline

Prior Authorization Guideline

Guideline ID	GL-231290
Guideline Name	Tryngolza (olezarsen sodium)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	2/20/2025
P&T Revision Date:	

1 . Indications

Drug Name: Tryngolza (olezarsen sodium)
Familial chylomicronemia syndrome (FCS) Indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)

2 . Criteria

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

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRYNGOLZA	OLEZARSEN SOD SUBCUT SOLN AUTO-INJECT 80 MG/0.8ML (BASE EQ)	3090626530D540	Brand

Approval Criteria

1 - Diagnosis of familial chylomicronemia syndrome (FCS) (type 1 hyperlipoproteinemia)

AND

2 - One of the following:

2.1 Genetic confirmation of biallelic pathogenic variants in FCS-causing genes (i.e., LPL, GPIHBP1, APOA5, APOC2, or LMF1)

OR

2.2 A North American FCS (NAFCS) Score of greater than or equal to 45 [4]

AND

3 - Both of the following:

3.1 One of the following:

3.1.1 Patient has tried or will receive treatment with standard of care triglyceride lowering therapy (i.e., prescription omega-3 fatty acid and a fibrate)

OR

3.1.2 Patient has an intolerance to standard of care triglyceride lowering therapy (i.e., prescription omega-3 fatty acid and a fibrate)

AND

3.2 Baseline fasting triglyceride levels are greater than or equal to 880 mg/dL prior to treatment with requested drug

AND

4 - Requested drug will be used as adjunct to a low-fat diet

AND

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

- Cardiologist
- Endocrinologist
- Gastroenterologist
- Lipid specialist (lipidologist)

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

Product Name	Generic Name	GPI	Brand/Generic
TRYNGOLZA	OLEZARSEN SOD SUBCUT SOLN AUTO-INJECT 80 MG/0.8ML (BASE EQ)	3090626530D540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in triglyceride levels from baseline)

3 . References

1. Tryngolza Prescribing Information. Ionis Pharmaceuticals, Inc. Carlsbad, CA 92010. December 2024.
2. Stroes ESG, Alexander VJ, Karwatowska-Prokopczuk E, et al. Olezarsen, Acute Pancreatitis, and Familial Chylomicronemia Syndrome. N Engl J Med. 2024;390(19):1781-1792. doi:10.1056/NEJMoa2400201
3. Study Details | A Study of Olezarsen (Formerly Known as AKCEA-APOCIII-LRx) Administered to Patients With Familial Chylomicronemia Syndrome (FCS) | ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT04568434. Accessed January 10, 2024.
4. Hegele RA, Ahmad Z, Ashraf A, et al. Development and validation of clinical criteria to identify familial chylomicronemia syndrome (FCS) in North America. J Clin Lipidol. Published online November 12, 2024. doi:10.1016/j.jacl.2024.09.008

4 . Revision History

Date	Notes
4/2/2025	Copied from Quartz Comm to EHB

Ultomiris (ravulizumab-cwvz)

Prior Authorization Guideline

Guideline ID	GL-250199
Guideline Name	Ultomiris (ravulizumab-cwvz)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/14/2019
P&T Revision Date:	3/19/2025

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)

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)

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]

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

1. Ultomiris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. March 2024.
2. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.

3. Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current Treatment of Myasthenia Gravis. Journal of Clinical Medicine. 2022;11(6):1597. doi:https://doi.org/10.3390/jcm11061597

4 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-231287
Guideline Name	Urea Cycle Disorder Agents - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	4/2/2025

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

1. Buphenyl Prescribing Information. Ucyclyd Pharma, Inc. Scottsdale, AZ. April 2023.
2. 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.
3. 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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4 . Revision History

Date	Notes
4/2/2025	Copied from Quartz Comm to Quartz EHB

Prior Authorization Guideline

Guideline ID	GL-286195
Guideline Name	Ustekinumab
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/12/2025

1 . Indications

Drug Name: Otulfi (Ustekinumab-AAUZ), Steqeyma (Ustekinumab-STBA), Yesintek (Ustekinumab-KFCE)
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: Otulfi IV (Ustekinumab-AAUZ), Steqeyma IV (Ustekinumab-STBA), Yesintek IV (Ustekinumab-KFCE)

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:Otulfi SC 45 mg/0.5 mL, Yesintek SC 45 mg/0.5 mL, Steqeyma 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
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058579E520	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058577E520	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058578E520	Brand
YESINTEK	USTEKINUMAB-KFCE SUBCUTANEOUS SOLN 45 MG/0.5ML	90250585782020	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

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

Product Name:Otulfi SC 90 mg/1 mL, Yesintek SC 90 mg/1 mL, Steqeyma 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
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 90 MG/ML	9025058579E540	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 90 MG/ML	9025058577E530	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 90 MG/ML	9025058578E540	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

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

Product Name:Otulfi SC, Yesintek SC, Steqeyma SC

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

Product Name	Generic Name	GPI	Brand/Generic
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058579E520	Brand
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 90 MG/ML	9025058579E540	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058577E520	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 90 MG/ML	9025058577E530	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058578E520	Brand
YESINTEK	USTEKINUMAB-KFCE SUBCUTANEOUS SOLN 45 MG/0.5ML	90250585782020	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 90 MG/ML	9025058578E540	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	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Otulfi SC 45 mg/0.5 mL, Yesintek SC 45 mg/0.5 mL, Steqeyma 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
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058579E520	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058577E520	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058578E520	Brand
YESINTEK	USTEKINUMAB-KFCE SUBCUTANEOUS SOLN 45 MG/0.5ML	90250585782020	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

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

Product Name:Otulfi SC 90 mg/1 mL, Yesintek SC 90 mg/1 mL, Steqeyma 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
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 90 MG/ML	9025058579E540	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 90 MG/ML	9025058577E530	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 90 MG/ML	9025058578E540	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

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

Product Name:Otulfi SC, Yesintek SC, Steqeyma SC	
Diagnosis	Psoriatic arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058579E520	Brand
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 90 MG/ML	9025058579E540	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058577E520	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 90 MG/ML	9025058577E530	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058578E520	Brand
YESINTEK	USTEKINUMAB-KFCE SUBCUTANEOUS SOLN 45 MG/0.5ML	90250585782020	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 90 MG/ML	9025058578E540	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	Approve at GPI 8 with Ignore Drug Status of I.

Product Name:Otulfi IV, Yesintek IV, Steqeyma IV	
Diagnosis	Crohn's Disease
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTULFI	USTEKINUMAB-AAUZ IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INF)	52504070802020	Brand
STEQEYMA	USTEKINUMAB-STBA IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INF)	52504070782020	Brand
YESINTEK	USTEKINUMAB-KFCE IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INF)	52504070792020	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

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

Product Name:Otulfi SC, Yesintek SC, Steqeyma 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

OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058579E520	Brand
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 90 MG/ML	9025058579E540	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058577E520	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 90 MG/ML	9025058577E530	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058578E520	Brand
YESINTEK	USTEKINUMAB-KFCE SUBCUTANEOUS SOLN 45 MG/0.5ML	90250585782020	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 90 MG/ML	9025058578E540	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

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

Product Name:Otulfi IV, Yesintek IV, Steqeyma IV	
Diagnosis	Ulcerative Colitis
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTULFI	USTEKINUMAB-AAUZ IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INF)	52504070802020	Brand

STEQEYMA	USTEKINUMAB-STBA IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INF)	52504070782020	Brand
YESINTEK	USTEKINUMAB-KFCE IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INF)	52504070792020	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

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

Product Name:Otulfi SC, Yesintek SC, Steqeyma SC	
Diagnosis	Ulcerative Colitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058579E520	Brand
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 90 MG/ML	9025058579E540	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058577E520	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 90 MG/ML	9025058577E530	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058578E520	Brand
YESINTEK	USTEKINUMAB-KFCE SUBCUTANEOUS SOLN 45 MG/0.5ML	90250585782020	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 90 MG/ML	9025058578E540	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

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

Product Name:Otulfi SC, Yesintek SC, Steqeyma 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
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058579E520	Brand
OTULFI	USTEKINUMAB-AAUZ SOLN PREFILLED SYRINGE 90 MG/ML	9025058579E540	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058577E520	Brand
STEQEYMA	USTEKINUMAB-STBA SOLN PREFILLED SYRINGE 90 MG/ML	9025058577E530	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058578E520	Brand
YESINTEK	USTEKINUMAB-KFCE SUBCUTANEOUS SOLN 45 MG/0.5ML	90250585782020	Brand
YESINTEK	USTEKINUMAB-KFCE SOLN PREFILLED SYRINGE 90 MG/ML	9025058578E540	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	Approve at GPI 8 with Ignore Drug Status of I.

3 . References

1. Stelara prescribing information. Janssen Biotech, Inc. Horsham PA. March 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. 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.
6. 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.
7. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
8. 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
6/12/2025	Removed all Stelara GPI, Changed to biosimilar products

Venclexta (venetoclax)

Prior Authorization Guideline

Guideline ID	GL-250200
Guideline Name	Venclexta (venetoclax)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	6/22/2016
P&T Revision Date:	2/20/2025

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: [2]

- 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

1. Venclexta Prescribing Information. AbbVie, Inc. North Chicago, IL. July 2024.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on February 3, 2025.

4 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Veopoz (pozelimab-bbfg)

Prior Authorization Guideline

Guideline ID	GL-163403
Guideline Name	Veopoz (pozelimab-bbfg)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. 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-163405
Guideline Name	Voranigo (Vorasidenib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. Voranigo Prescribing Information. Servier Pharmaceuticals LLC, , Boston, MA 02210. August 2024.
2. Mellinghoff IK, van den Bent MJ, Blumenthal DT, Touat M, Peters KB, Clarke J, Mendez J, Yust-Katz S, Welsh L, Mason WP, Ducray F, Umemura Y, Nabors B, Holdhoff M, Hottinger AF, Arakawa Y, Sepulveda JM, Wick W, Soffietti R, Perry JR, Giglio P, de la Fuente M, Maher EA, Schoenfeld S, Zhao D, Pandya SS, Steelman L, Hassan I, Wen PY, Cloughesy TF; INDIGO Trial Investigators. Vorasidenib in IDH1- or IDH2-Mutant Low-Grade Glioma. N Engl J Med. 2023 Aug 17;389(7):589-601. doi: 10.1056/NEJMoa2304194. Epub 2023 Jun 4. PMID: 37272516.
3. NCCN Clinical Practice Guidelines in Oncology. Central Nervous System Cancers Version 3.2024 Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf Accessed October 11, 2024.

4 . Revision History

Date	Notes

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

Votrient (pazopanib)

Prior Authorization Guideline

Guideline ID	GL-250201
Guideline Name	Votrient (pazopanib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/16/2010
P&T Revision Date:	3/19/2025

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

A. Votrient is an active drug in anthracycline pretreated STS patients with an increase in median PFS of 13 weeks. [3]

4 . References

1. Votrient Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. January 2024.
2. National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Kidney cancer v.3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed February 28, 2025.
3. 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.

4. National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Soft tissue sarcoma v.4.2024. Available at: http://www.nccn.org/professionals/physician_gls/PDF/sarcoma.pdf. Accessed February 28, 2025.

5 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-249214
Guideline Name	Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	6/19/2019
P&T Revision Date:	2/20/2025

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 Presence of a transthyretin (TTR) mutation (e.g., V122I) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits

OR

2.3 Both of the following:

- Cardiac magnetic resonance imaging suggestive of amyloidosis or scintigraphy scan suggestive of amyloidosis
- Absence of light-chain amyloidosis

AND

3 - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure [2]

AND

4 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Diflunisal)

AND

5 - 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 continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

2 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Diflunisal)

AND

3 - Prescribed by or in consultation with a cardiologist

3 . References

1. Vyndaqel and Vyndamax prescribing information. Pfizer, Inc. New York, NY. April 2023.
2. Mauer MS, Schwartz JH, Gundapeneni B, et al. Tafamadis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018; 379:1007-16.
3. Gillmore JD, Maurer MS, Falk RH, et al. Nonbiopsy diagnosis of cardiac transthyretin amyloidosis. Circulation. 2016; 133:2404-12.
4. 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
4/30/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-278255
Guideline Name	Xiaflex (collagenase clostridium histolyticum)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	6/15/2025
P&T Approval Date:	2/25/2016
P&T Revision Date:	4/16/2025

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

A. 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]
B. 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]
C. 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

1. Xiaflex Prescribing Information. Endo Pharmaceuticals, Inc. Malvern, PA. August 2022.

5 . Revision History

Date	Notes
5/22/2025	Quartz guideline copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-165070
Guideline Name	Xifaxan (rifaximin)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	2/12/2025
P&T Approval Date:	
P&T Revision Date:	7/17/2024

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	
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]

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 a Tricyclic Antidepressant (e.g., amitriptyline)

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 a Tricyclic Antidepressant (e.g., amitriptyline)

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]

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

3 . Endnotes

A. Antibiotic treatment should be avoided in diarrhea caused by enterohemorrhagic E. coli. [6]
B. 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]
C. 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]
D. 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]
E. 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]
F. 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]
G. 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]
H. 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]
I. The recommended dose of Xifaxan for IBS-D is one 550 mg tablet taken orally three times a day for 14 days. [1]
J. 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]
K. 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]
L. 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]

M. 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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5 . Revision History

Date	Notes
2/12/2025	Quartz EHB copied to mirrow OptumRx-EHB

Prior Authorization Guideline

Guideline ID	GL-250202
Guideline Name	Xiidra (lifitegrast)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	8/18/2016
P&T Revision Date:	3/19/2025

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

A. 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

1. Xiidra Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2020.
2. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Committee. Dry Eye Syndrome PPP - 2018. November 2018. https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018. Accessed January 28, 2022.

5 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-250203
Guideline Name	Zelboraf (vemurafenib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/21/2012
P&T Revision Date:	3/19/2025

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

A. 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

1. Zelboraf Prescribing Information. Genentech USA, Inc., May 2020.
2. 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 28, 2025

5 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Prior Authorization Guideline

Guideline ID	GL-250204
Guideline Name	Zokinvy (lonafarnib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	2/18/2021
P&T Revision Date:	2/20/2025

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

1. Zokinvy Prescribing Information. Eiger BioPharmaceuticals, Inc. Palo Alto, CA. March 2024.

4 . Revision History

Date	Notes
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx

Zydelig (idelalisib)

Prior Authorization Guideline

Guideline ID	GL-163433
Guideline Name	Zydelig (idelalisib)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA) • Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, 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

1. Zydelig Prescribing Information. Gilead Sciences, Inc. Foster City, CA. February 2022.
2. 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-250205
Guideline Name	Zytiga (abiraterone acetate) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZQHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	7/19/2013
P&T Revision Date:	3/19/2025

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

1. Zytiga Prescribing Information. Janssen Biotech Inc. Horsham, PA. November 2024.
2. 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
4/29/2025	Quartz Comm/EHB copied to mirrow OptumRx