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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.

January 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.

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Prior Authorization Guideline

Guideline ID	GL-160804
Guideline Name	Actimmune (interferon gamma-1b)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

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

2 . Criteria

Product Name: Actimmune	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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

Approval Criteria

1 - Diagnosis of one of the following:

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

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

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

Approval Criteria

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

3 . Background

Benefit/Coverage/Program Information
Effective date

Prior to 3/8/2023 Updates the effective date was 1/1/2021

4 . References

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

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160447
Guideline Name	Adalimumab*
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 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, 9, 10]:

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

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

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

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

HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML	6627001520D510	Brand
HADLIMA PUSHTOUCH	ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML	6627001520D520	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.4ML	6627001520E510	Brand
HADLIMA	ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE 40 MG/0.8ML	6627001520E520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML	6627001535F520	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML	6627001535F810	Brand
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML	6627001535F820	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

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

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

AND

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

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

AND
4 - Prescribed by or in consultation with a gastroenterologist

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

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

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

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

Approval Criteria

1 - One of the following:

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

OR

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

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

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

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

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

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

Approval Criteria

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

AND

2 - Prescribed by or in consultation with a dermatologist

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

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

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

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

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

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

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

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

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

Approval Criteria

1 - Diagnosis of non-infectious uveitis

AND

2 - Uveitis is classified as one of the following:

- intermediate
- posterior
- panuveitis

AND

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

- ophthalmologist
- rheumatologist

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

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

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

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

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

3 . References

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

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

Prior Authorization Guideline

Guideline ID	GL-160805
Guideline Name	Administrative Non-Formulary & Excluded Drug Exceptions Process
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160806
Guideline Name	Afinitor, Afinitor Disperz (everolimus) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

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

Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR + BC) Indicated for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole. **Neuroendocrine Tumors of Gastrointestinal or Lung Origin** Indicated for the treatment of adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors.
Drug Name: Torpenz (everolimus tablet)
Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC) Indicated for the treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery. **Subependymal Giant Cell Astrocytoma (SEGA)** Indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. **Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR + BC)** Indicated for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole.
Drug Name: Afinitor Disperz (everolimus tablet for oral suspension)
Subependymal Giant Cell Astrocytoma (SEGA) Indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. The effectiveness of Afinitor Disperz is based on demonstration of durable objective response, as evidenced by reduction in SEGA tumor volume. Improvement in disease-related symptoms and overall survival in patients with SEGA and TSC has not been demonstrated. **Tuberous Sclerosis Complex (TSC) Associated Partial-onset Seizures** Indicated for the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures

2 . Criteria

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

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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

Approval Criteria

1 - Diagnosis of progressive neuroendocrine tumors of pancreatic origin

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

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

Product Name: Brand Afinitor, Generic everolimus tablet, Torpenz (off-label)

Diagnosis	Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

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

Approval Criteria

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

AND

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

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

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

Approval Criteria

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

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

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

AND

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

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

Guideline Type	Prior Authorization

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

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

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

- Sutent (sunitinib)
- Nexavar (sorafenib)

AND

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

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

Product Name: Brand Afinitor, Generic everolimus tablet, Torpenz (off-label)

Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

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

Approval Criteria

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

AND

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

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

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

Approval Criteria

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

AND

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

- Sutent (sunitinib)
- Nexavar (sorafenib)

AND

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

AND

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

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

Product Name: Brand Afinitor, Generic everolimus tablet, Torpenz	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)

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

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

Approval Criteria

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

AND

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

AND

3 - Prescribed by or in consultation with a nephrologist

Product Name: Brand Afinitor, Generic everolimus tablet, Torpenz	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)

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

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

Approval Criteria

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

AND

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

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

Product Name	Generic Name	GPI	Brand/Generic

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

Approval Criteria

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

AND

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

AND

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

AND

4 - Prescribed by or in consultation with a nephrologist

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

Product Name	Generic Name	GPI	Brand/Generic

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

Approval Criteria

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

AND

2 - Patient is 1 year of age or older

AND

3 - One of the following:

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

OR

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

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

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

TORPENZ	EVEROLIMUS TAB 5 MG	21532530000320	Generic
TORPENZ	EVEROLIMUS TAB 7.5 MG	21532530000325	Generic
TORPENZ	EVEROLIMUS TAB 10 MG	21532530000330	Generic

Approval Criteria

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

AND

2 - One of the following:

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

OR

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

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

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

AFINITOR DISPERZ	EVEROLIMUS TAB FOR ORAL SUSP 5 MG	21532530007340	Brand

Approval Criteria

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

AND

2 - Patient is 1 year of age or older

AND

3 - One of the following:

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

OR

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

AND

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

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

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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

Approval Criteria

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

AND

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

- Femara (letrozole)
- Arimidex (anastrozole)

AND

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

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

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

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

Approval Criteria

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

AND

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

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

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

Approval Criteria

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

AND

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

- Femara (letrozole)
- Arimidex (anastrozole)

AND

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

AND

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

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

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

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

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

Approval Criteria

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

AND

2 - One of the following:

- Unresectable, locally advanced disease
- Metastatic disease

AND

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

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

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

Approval Criteria

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

AND

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

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

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

Approval Criteria

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

AND

2 - One of the following:

- Unresectable, locally advanced disease
- Metastatic disease

AND

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

AND

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

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

Guideline Type	Prior Authorization

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

Approval Criteria

1 - Diagnosis of TSC-associated partial-onset seizures

AND

2 - Patient is 2 years of age or older

AND

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

AND

4 - Prescribed by or in consultation with a neurologist

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

Guideline Type	Prior Authorization

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

Approval Criteria

1 - Patient shows reduction in seizure frequency while on therapy

AND

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

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

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

Approval Criteria

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

AND

2 - Patient is 2 years of age or older

AND

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

AND

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

AND

5 - Prescribed by or in consultation with a neurologist

3 . References

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

4 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160807
Guideline Name	Afrezza (insulin human, inhalation powder) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

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

2 . Criteria

Product Name: Afrezza	
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of type 1 diabetes mellitus

AND

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

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

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

- Physical impairment

- Visual impairment
- Lipohypertrophy

AND

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

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Afrezza will NOT be approved in patients:

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

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

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

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

Approval Criteria

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

AND

2 - Patient demonstrates positive clinical response to therapy

AND

3 - Both of the following: [1]

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

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

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

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

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of type 1 diabetes mellitus

AND

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

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

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

- Physical impairment
- Visual impairment
- Lipohypertrophy

AND

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

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Afrezza will NOT be approved in patients:

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

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

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

Approval Criteria

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

AND

2 - Patient demonstrates positive clinical response to therapy

AND

3 - Both of the following: [1]

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

3 . Endnotes

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

4 . References

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

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160808
Guideline Name	Akeega (niraparib and abiraterone) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 2023.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160809
Guideline Name	Alecensa (alectinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

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

2 . Criteria

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

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

Approval Criteria

1 - Diagnosis of non-small cell lung cancer

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

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

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

Approval Criteria

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

3 . References

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

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160810
Guideline Name	Alfa Interferons
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

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

AIDS-Related Kaposi's Sarcoma Indicated for the treatment of selected patients 18 years of age or older with AIDS-Related Kaposi's Sarcoma. The likelihood of response to Intron A therapy is greater in patients who are without systemic symptoms, who have limited lymphadenopathy and who have a relatively intact immune system as indicated by total CD4 count.

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

Chronic Hepatitis B Indicated for the treatment of chronic hepatitis B in patients 1 year of age or older with compensated liver disease. Patients who have been serum HBsAg positive for at least 6 months and have evidence of HBV replication (serum HBeAg positive) with elevated serum ALT are candidates for treatment. Studies in these patients demonstrated that Intron A therapy can produce virologic remission of this disease (loss of serum HBeAg), and normalization of serum aminotransferases. Intron A therapy resulted in the loss of serum HBsAg in some responding patients. Prior to initiation of Intron A therapy, it is recommended that a liver biopsy be performed to establish the presence of chronic hepatitis and the extent of liver damage. The physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before Intron A treatment of patients with chronic hepatitis B: - No history of hepatic encephalopathy, variceal bleeding, ascites, or other signs of clinical decompensation - Bilirubin normal - Albumin stable and within normal limits - Prothrombin Time - adults < 3 seconds prolonged, pediatrics less than or equal to 2 seconds prolonged - WBC greater than or equal to 4,000/mm^3 - Platelets - adults greater than or equal to 100,000/mm^3, pediatrics greater than or equal to 150,000/mm^3. Patients with

causes of chronic hepatitis other than chronic hepatitis B or chronic hepatitis C should not be treated with Intron A. CBC and platelet counts should be evaluated prior to initiation of Intron A therapy in order to establish baselines for monitoring potential toxicity. These tests should be repeated at treatment Weeks 1, 2, 4, 8, 12, and 16. Liver function tests, including serum ALT, albumin, and bilirubin, should be evaluated at treatment Weeks 1, 2, 4, 8, 12, and 16. HBeAg, HBsAg, and ALT should be evaluated at the end of therapy, as well as 3- and 6-months post-therapy, since patients may become virologic responders during the 6-month period following the end of treatment. In clinical studies in adults, 39% (15/38) of responding patients lost HBeAg 1 to 6 months following the end of Intron A therapy. Of responding patients who lost HBsAg, 58% (7/12) did so 1 to 6 months post-treatment. A transient increase in ALT greater than or equal to 2 x baseline value (flare) can occur during Intron A therapy for chronic hepatitis B. In clinical trials in adults and pediatrics, this flare generally occurred 8 to 12 weeks after initiation of therapy and was more frequent in Intron A responders (adults 63%, 24/38; pediatrics 59%, 10/17) than in non-responders (adults 27%, 13/48; pediatrics 35%, 19/55). However, in adults and pediatrics, elevations in bilirubin 3 mg/dL (2 times ULN) occurred infrequently (adults 2%, 2/86; pediatrics 3%, 2/72) during therapy. When ALT flare occurs, in general, Intron A therapy should be continued unless signs and symptoms of liver failure are observed. During ALT flare, clinical symptomatology and liver function tests including ALT, prothrombin time, alkaline phosphatase, albumin, and bilirubin, should be monitored at approximately 2-week intervals.

Drug Name: Pegasys (peginterferon alfa-2a)

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

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

2 . Criteria

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

Guideline Type	Prior Authorization

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

Approval Criteria

1 - Diagnosis of chronic hepatitis C

AND

2 - Patients without decompensated liver disease**

AND

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

AND

4 - One of the following:

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

AND

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

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

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

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

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

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient without decompensated liver disease**

AND

3 - One of the following:

3.1 Used in combination with one of the following:

- Sovaldi (sofosbuvir)
- Ribavirin

OR

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

AND

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

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

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

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

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

Approval Criteria

1 - Patient has an undetectable HCV RNA at week 24

AND

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

AND

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

AND

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

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

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

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

Approval Criteria

1 - Diagnosis of chronic hepatitis B infection

AND

2 - Patients without decompensated liver disease**

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

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

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

Approval Criteria

1 - Diagnosis of condylomata acuminata (genital or perianal)

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

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

Approval Criteria

1 - One of the following:

1.1 Diagnosis of hairy cell leukemia

OR

1.2 Diagnosis of AIDS-related Kaposi's sarcoma

OR

1.3 Both of the following:

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

OR

1.4 Diagnosis of malignant melanoma

OR

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

OR

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

3 . References

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

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160811
Guideline Name	Alpha-1 Proteinase Inhibitors
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

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

clinically evident emphysema due to severe hereditary deficiency of Alpha1-PI, also known as alpha1-antitrypsin (AAT) deficiency. Limitations of Use: The effect of augmentation therapy with Glassia or any Alpha1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with Glassia are not available. Glassia is not indicated as therapy for lung disease in patients in whom severe Alpha1-PI deficiency has not been established.

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

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

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

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

2 . Criteria

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

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

Approval Criteria

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

AND

2 - Diagnosis of emphysema [A]

AND

3 - One of the following:

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

OR

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

AND

4 - One of the following:

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

OR

4.2 Patient has a concomitant diagnosis of necrotizing panniculitis

AND

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

AND

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

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

OR

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

OR

6.3 Patient has a concomitant diagnosis of necrotizing panniculitis

AND

7 - Patient is NOT a current smoker [C]

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

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

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

3 . Endnotes

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

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

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

4 . References

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

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160812
Guideline Name	Ampyra (dalfampridine) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

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

2 . Criteria

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

Guideline Type	Prior Authorization

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

Approval Criteria

1 - Diagnosis of multiple sclerosis [A]

AND

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

AND

3 - One of the following:

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

AND

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

AND

5 - Prescribed by or in consultation with a neurologist

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

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

Approval Criteria

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

AND

2 - One of the following:

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

AND

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

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

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

Approval Criteria

1 - Diagnosis of multiple sclerosis [A]

AND

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

AND

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

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

AND

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

AND

5 - Prescribed by or in consultation with a neurologist

3 . Endnotes

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

4 . References

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

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-158642
Guideline Name	Anticonvulsants
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

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

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

2 . Criteria

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

Guideline Type	Step Therapy

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

Approval Criteria

1 - Both of the following:

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

AND

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

OR

2 - For continuation of prior therapy

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

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

Approval Criteria

1 - Both of the following:

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

AND

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

OR

2 - For continuation of prior therapy

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

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

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

Approval Criteria

1 - Both of the following:

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

AND

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

OR

2 - For continuation of prior therapy

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

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

Approval Criteria

1 - Both of the following:

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

AND

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

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

OR

2 - For continuation of prior therapy

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

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

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

Approval Criteria

1 - Both of the following:

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

AND

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

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

OR

2 - For continuation of prior therapy

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

Product Name	Generic Name	GPI	Brand/Generic

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

Approval Criteria

1 - Both of the following:

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

AND

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

OR

2 - For continuation of prior therapy

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

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

Approval Criteria

1 - Both of the following:

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

AND

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

OR

2 - For continuation of prior therapy

3 . References

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

Prior Authorization Guideline

Guideline ID	GL-158851
Guideline Name	Antidepressants
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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. September 2021.
2. Fetzima Prescribing Information. Allergan USA, Inc. Madison, NJ. September 2021.

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.

Prior Authorization Guideline

Guideline ID	GL-160813
Guideline Name	Antiemetics Quantity Limit Overrides
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Akynzeo (netupitant/palonosetron)
Chemotherapy-induced nausea and vomiting 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 an oral 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.
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), Zuplenz (ondansetron oral soluble film)
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, Generic dronabinol, Brand Emend, Generic aprepitant, granisetron, Brand Marinol, Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Sancuso, Sustol, Varubi, or Zuplenz	
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
ZUPLENZ	ONDANSETRON ORAL SOLUBLE FILM 4 MG	50250065008220	Brand
ZUPLENZ	ONDANSETRON ORAL SOLUBLE FILM 8 MG	50250065008240	Brand
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, Generic ondansetron ODT, or Zuplenz	
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
ZUPLENZ	ONDANSETRON ORAL SOLUBLE FILM 4 MG	50250065008220	Brand
ZUPLENZ	ONDANSETRON ORAL SOLUBLE FILM 8 MG	50250065008240	Brand

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, Generic ondansetron ODT, or Zuplenz	
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
ZUPLENZ	ONDANSETRON ORAL SOLUBLE FILM 4 MG	50250065008220	Brand
ZUPLENZ	ONDANSETRON ORAL SOLUBLE FILM 8 MG	50250065008240	Brand
ONDANSETRON HCL	ONDANSETRON HCL TAB 24 MG	50250065050340	Generic
ONDANSETRON HYDROCHLORIDE	ONDANSETRON HCL ORAL SOLN 4 MG/5ML	50250065052070	Generic

Approval Criteria

1 - Diagnosis of nausea and vomiting due to pregnancy (i.e., hyperemesis gravidarum) [10, 16]

AND

2 - History of failure, contraindication, or intolerance to at least one of the following: [A]

- doxylamine
- metoclopramide (Reglan)
- prochlorperazine (Compazine)
- promethazine (Phenergan)
- pyridoxine (Vitamin B6)

AND

3 - Patient has had at least a partial response to therapy at a dose within the quantity limit

3 . Background

Benefit/Coverage/Program Information
Quantity Limit These products are subject to a standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.

4 . Endnotes

A. Treatment of nausea and vomiting of pregnancy with vitamin B6 or vitamin B6 plus doxylamine is safe and effective and should be considered first-line pharmacotherapy (Level A Evidence). Treatment of nausea and vomiting of pregnancy with ginger has shown beneficial effects and can be considered as a nonpharmacologic option (Level B

Evidence). Several types of dopamine antagonists can be used for the treatment of nausea and vomiting of pregnancy such as promethazine, prochlorperazine, and metoclopramide. Antihistamines (such as dimenhydrinate and diphenhydramine) have been shown to be effective in controlling nausea and vomiting symptoms of pregnancy and are frequently used. Evidence is limited on the safety or efficacy of the 5-HT3 inhibitors (e.g. ondansetron) for nausea and vomiting of pregnancy. The ACOG recommends discussing the available data with patients as well as weighing the risks and benefits in women less than 10 weeks of gestation. Because of their limited data, they should not be advocated for first-line use until agents with established safety and efficacy have been tried and have failed. Treatment of severe nausea and vomiting of pregnancy or hyperemesis gravidarum with methylprednisolone may be efficacious in refractory cases; however, the risk profile of methylprednisolone suggests it should be a treatment of last resort (Level B Evidence). [16]

5 . References

1. Akynzeo prescribing information. Helsinn Therapeutics (U.S.), Inc. Iselin, NJ. February 2023.
2. Anzemet prescribing information. Validus Pharmaceuticals LLC. Parsippany, NJ. September 2021.
3. Emend prescribing information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. May 2022.
4. Granisetron prescribing information. Ascend Laboratories. Montvale, NJ. July 2022.
5. Marinol prescribing information. AbbVie Inc. North Chicago, IL. August 2017.
6. Sancuso prescribing information. Kyowa Kirin, Inc. Bedminster, NJ. December 2022.
7. Varubi prescribing information. TerSera Therapeutics LLC. Deerfield, IL. August 2020.
8. Zofran prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2020.
9. Zuplenz prescribing information. Fortovia Therapeutics, Inc. Raleigh, NC. May 2020.
10. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically. Available by subscription at: http://www.thomsonhc.com/. Accessed September 9, 2021.
11. Fauser AA, Russ W, Bischoff M. Oral dolasetron mesilate (MDL 73,147EF) for the control of emesis during fractionated total-body irradiation and high-dose cyclophosphamide in patients undergoing allogeneic bone marrow transplantation. Support Care Cancer. 1997 May;5(3):219-22.
12. Basch E, Prestrud AA, Hesketh PJ, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clinic Oncol. 2011;29(31):4189-98.
13. AHFS Drug Information website. Available at: https://online.lexi.com/lco/action/doc/retrieve/docid/250/413041. Accessed September 9, 2021.
14. Fujii Y, Tanaka H, Kawasaki T. Preoperative oral granisetron for the prevention of postoperative nausea and vomiting after breast surgery. Eur J Surg. 2001 Mar;167(3):184-7.
15. Fujii Y, Tanaka H, Kawasaki T. Prophylaxis with oral granisetron for the prevention of nausea and vomiting after laparoscopic cholecystectomy: a prospective randomized study. Arch Surg. 2001 Jan;136(1):101-4.

16. ACOG Practice Bulletin. Nausea and vomiting of pregnancy. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2018; 103(1):15-30.
17. Sustol prescribing information. Heron Therapeutics. San Diego, CA. May 2023.

6 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-158644
Guideline Name	AntiGout Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Uloric (febuxostat)
Gout A xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable. Uloric is not recommended for the treatment of asymptomatic hyperuricemia.
Drug Name: Mitigare (colchicine) capsule
Prophylaxis of gout flares Indicated for prophylaxis of gout flares in adults. Limitation of Use: The safety and effectiveness of Mitigare for acute treatment of gout flares during prophylaxis has not been studied. Mitigare is not an analgesic medication and should not be used to treat pain from other causes.
Drug Name: Colcrys (colchicine) tablet
Prophylaxis of Gout Flares Indicated for the prophylaxis of gout flares. **Treatment of Gout Flares** Indicated for treatment of acute gout flares when taken at the first sign of a flare.

Familial Mediterranean Fever (FMF) Indicated in adults and children 4 years or older for treatment of FMF.

Drug Name: Allopurinol

Gout Indicated in: 1) the management of patients with signs and symptoms of primary or secondary gout (acute attacks, tophi, joint destruction, uric acid lithiasis, and/or nephropathy). 2) the management of patients with leukemia, lymphoma and malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels. Treatment with allopurinol should be discontinued when the potential for over production of uric acid is no longer present. 3) the management of patients with recurrent calcium oxalate calculi whose daily uric acid excretion exceeds 800 mg/day in male patients and 750 mg/day in female patients. Therapy in such patients should be carefully assessed initially and reassessed periodically to determine in each case that treatment is beneficial and that the benefits outweigh the risks.

2 . Criteria

Product Name: generic febuxostat, Uloric	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ULORIC	FEBUXOSTAT TAB 40 MG	68000030000320	Brand
ULORIC	FEBUXOSTAT TAB 80 MG	68000030000330	Brand
FEBUXOSTAT	FEBUXOSTAT TAB 40 MG	68000030000320	Generic
FEBUXOSTAT	FEBUXOSTAT TAB 80 MG	68000030000330	Generic

Approval Criteria

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

AND

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

Product Name: Mitigare, Brand Colcrys	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
MITIGARE	COLCHICINE CAP 0.6 MG	68000020000120	Generic
COLCRYS	COLCHICINE TAB 0.6 MG	68000020000310	Brand

Approval Criteria

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

AND

2 - Trial and failure of a minimum 30 days supply within past 180 days, or intolerance to generic colchicine tablets

Product Name: Brand Allopurinol 200mg tablet	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ALLOPURINOL	ALLOPURINOL TAB 200 MG	68000010000307	Brand

Approval Criteria

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

AND

2 - Trial and failure (of a minimum 30-day supply), or intolerance to generic allopurinol

3 . References

1. Uloric Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. April 2023.
2. Mitigare Prescribing Information. Specialty USA Inc. Columbus, OH. May 2024.
3. Colchicine Tablets Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. December 2021.
4. Allopurinol Prescribing Information. Camber Pharmaceuticals, Inc. Piscataway, NJ 08854. August 2023.

Prior Authorization Guideline

Guideline ID	GL-160814
Guideline Name	Antimalarial Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Qualaquin (quinine sulfate)
Malaria Indicated only for treatment of uncomplicated Plasmodium falciparum malaria. Quinine sulfate has been shown to be effective in geographical regions where resistance to chloroquine has been documented. Limitations of Use: 1) Not approved for patients with severe or complicated P. falciparum malaria. 2) Not approved for prevention of malaria. 3) Not indicated for the prevention or treatment of nocturnal leg cramps.

2 . Criteria

Product Name: Brand Qualaquin, Generic quinine sulfate	
Diagnosis	Nocturnal Leg Cramps*

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QUALAQUIN	QUININE SULFATE CAP 324 MG	13000060100119	Brand
QUININE SULFATE	QUININE SULFATE CAP 324 MG	13000060100119	Generic

Approval Criteria

1 - Requests for coverage when used solely for the treatment or prevention of nocturnal leg cramps are not authorized and will not be approved [1, C]

Notes	*Nocturnal leg cramp is an off-label use.

Product Name: Brand Qualaquin, Generic quinine sulfate	
Diagnosis	Malaria
Approval Length	7 days [1]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QUALAQUIN	QUININE SULFATE CAP 324 MG	13000060100119	Brand
QUININE SULFATE	QUININE SULFATE CAP 324 MG	13000060100119	Generic

Approval Criteria

1 - Diagnosis of uncomplicated malaria

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Treatment in areas of chloroquine-sensitive malaria [2-4, A]*

AND **2.1.2** Trial and failure, contraindication or intolerance to one of the following: • chloroquine • hydroxychloroquine **OR** **2.2** Treatment in areas of chloroquine-resistant malaria [2-4, B]*	
Notes	*Call the Malaria Hotline (770-488-7788) for additional information if n eeded.

3 . Endnotes

A. Areas of chloroquine-sensitive malaria include: Central America west of the Panama Canal, Haiti and the Dominican Republic. [2-4]
B. Areas of chloroquine-resistant malaria include: Southeast Asia, and all malarious regions except those specified as chloroquine-sensitive listed in Endnote A. [2-4]
C. Quinine is not approved for and should not be used for the prophylaxis or treatment of nocturnal leg cramps. Quinine may cause unpredictable serious and life-threatening hematologic reactions including thrombocytopenia and hemolytic-uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP) in addition to hypersensitivity reactions, QT prolongation, serious cardiac arrhythmias including torsades de pointes, and other serious adverse events requiring medical intervention and hospitalization. Chronic renal impairment associated with the development of TTP, and fatalities have also been reported. The risk associated with the use of quinine in the absence of evidence of its effectiveness for treatment or prevention of nocturnal leg cramps, outweighs any potential benefit in treating and/or preventing this benign, self-limiting condition. [1]

4 . References

1. Qualaquin Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. August 2019.
2. Center for Disease Control Traveler's Health - Yellow Book 2020 edition. Chapter 4: Infectious diseases related to travel - malaria. Available at:

https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/malaria. Accessed May 1, 2024.
3. Center for Disease Control. Guideline for treatment of malaria in the United States. Available at: http://www.cdc.gov/malaria/diagnosis_treatment/treatment.html. Accessed May 1, 2024.
4. Griffith KS, Lewis LS, Mali S, Parise ME. Treatment of malaria in the United States. A systematic review. JAMA. 2007;297(20):2264-77.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-158852
Guideline Name	Apokyn
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Apokyn (apomorphine injection)
Parkinson's Disease Indicated for the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced Parkinson's disease. Apokyn has been studied as an adjunct to other medications.

2 . Criteria

Product Name: 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.

Prior Authorization Guideline

Guideline ID	GL-160815
Guideline Name	Atypical Antipsychotics - PA, ST
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
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.

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

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.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160816
Guideline Name	Azole Antifungals - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cresemba (isavuconazonium sulfate) capsules
Invasive Aspergillosis and Invasive Mucormycosis Indicated for adult and pediatric patients 6 years of age and older who weight 16 kilograms (kg) and greater for the treatment of invasive mucormycosis and invasive aspergillosis. Specimens for fungal culture and other relevant laboratory studies (including histopathology) to isolate and identify causative organism(s) should be obtained prior to initiating antifungal therapy. Therapy may be instituted before the results of the cultures and other laboratory studies are known. However, once these results become available, antifungal therapy should be adjusted accordingly.
Drug Name: Noxafil (posaconazole) tablets
Prophylaxis of Aspergillus infection Indicated for prophylaxis of invasive Aspergillus infections in adult and pediatric patients 2 years of age and older who weigh greater than 40 kg, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Prophylaxis of Candida infection Indicated for prophylaxis of invasive Candida infections in adult and pediatric patients 2 years of age and older who weigh greater than 40kg, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Treatment of Invasive Aspergillosis Indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older.

Drug Name: Noxafil (posaconazole) oral suspension

Prophylaxis of Aspergillus infection Indicated for prophylaxis of invasive Aspergillus infections in patients 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Prophylaxis of Candida infection Indicated for prophylaxis of invasive Candida infections in patients 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Oropharyngeal candidiasis Indicated for treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults and pediatric patients 13 years of age and older.

Drug Name: Noxafil PowderMix (posaconazole) for delayed-release oral suspension

Prophylaxis of Invasive Aspergillus and Candida Infections Indicated for the prophylaxis of invasive Aspergillus and Candida infections in pediatric patients 2 years of age and older who weigh 40 kg or less, who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Drug Name: Sporanox (itraconazole) capsules

Blastomycosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary

Histoplasmosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis

Aspergillosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy

Onychomycosis of the toenail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the toenail, with or without fingernail

involvement, due to dermatophytes (Tinea unguium)

Onychomycosis of the fingernail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)

Drug Name: Sporanox Pulse Pak (itraconazole)

Onychomycosis of the fingernail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)

Drug Name: Sporanox (itraconazole) oral solution

Oropharyngeal and esophageal candidiasis Indicated for the treatment of oropharyngeal and esophageal candidiasis.

Drug Name: Tolsura (itraconazole) capsules

Blastomycosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary.

Histoplasmosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis.

Aspergillosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy.

Drug Name: Vfend (voriconazole) oral suspension, Vfend (voriconazole) tablets

Invasive Aspergillosis Indicated in adults and pediatric patients (2 years of age and older) for the treatment of invasive aspergillosis (IA). In clinical trials, the majority of isolates recovered were Aspergillus fumigatus. There was a small number of cases of culture-proven disease due to species of Aspergillus other than A. fumigatus.

Candidemia in Non-neutropenic Patients and Other Deep Tissue Candida Infections Indicated in adults and pediatric patients (2 years of age and older) for the treatment of candidemia in non-neutropenic patients and the following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds.

Esophageal Candidiasis Indicated in adults and pediatric patients (2 years of age and older) for the treatment of esophageal candidiasis (EC) in adults and pediatric patients 2 years of age and older.

Scedosporiosis and Fusariosis Indicated for the treatment of serious fungal infections caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) and

Fusarium spp. including Fusarium solani, in adults and pediatric patients (2 years of age and older) intolerant of, or refractory to, other therapy.

2 . Criteria

Product Name: Cresemba oral capsule	
Approval Length	6 Months [17, B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CRESEMBA	ISAVUCONAZONIUM SULFATE CAP 186 MG (ISAVUCONAZOLE 100 MG)	11407030100120	Brand
CRESEMBA	ISAVUCONAZONIUM SULFATE CAP 74.5 MG (ISAVUCONAZOLE 40 MG)	11407030100105	Brand

Approval Criteria

1 - Diagnosis of one of the following fungal infections: [17]

- Invasive aspergillosis
- Invasive mucormycosis

AND

2 - Both of the following:

- Patient is 6 years of age or older
- Patient weighs 16 kilograms or greater

Product Name: Brand Sporanox capsules or generic itraconazole capsules	
Diagnosis	Systemic and topical fungal infections
Approval Length	6 months [5, 10-12, B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPORANOX	ITRACONAZOLE CAP 100 MG	11407035000120	Brand
ITRACONAZOLE	ITRACONAZOLE CAP 100 MG	11407035000120	Generic

Approval Criteria

1 - Diagnosis of a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis)

OR

2 - All of the following:

2.1 One of the following diagnoses:

- Tinea corporis (ring worm)
- Tinea cruris (jock itch)
- Tinea pedis (athlete's foot)
- Tinea capitis (scalp ringworm)
- Pityriasus versicolor

AND

2.2 One of the following:

2.2.1 The tinea infection is resistant to topical antifungal treatment

OR

2.2.2 Trial and failure, contraindication, or intolerance to oral terbinafine [3]

Product Name: Brand Sporanox capsules, generic itraconazole capsules, or Sporanox Pulse Pak	
Diagnosis	Fingernail Onychomycosis
Approval Length	1 Month [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPORANOX	ITRACONAZOLE CAP 100 MG	11407035000120	Brand
ITRACONAZOLE	ITRACONAZOLE CAP 100 MG	11407035000120	Generic
SPORANOX PULSEPAK	ITRACONAZOLE CAP 100 MG	11407035000120	Brand

Approval Criteria

1 - Diagnosis of fingernail onychomycosis as confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Fungal culture
- Nail biopsy

AND

2 - The patient's condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, wearing shoes, or appropriately manicuring nails) [4]

AND

3 - Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine

Product Name: Brand Sporanox capsules or generic itraconazole capsules	
Diagnosis	Toenail Onychomycosis
Approval Length	3 Month [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPORANOX	ITRACONAZOLE CAP 100 MG	11407035000120	Brand
ITRACONAZOLE	ITRACONAZOLE CAP 100 MG	11407035000120	Generic

Approval Criteria

1 - Diagnosis of toenail onychomycosis as confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Fungal culture
- Nail biopsy

AND

2 - The patient's condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, walking, standing, wearing shoes, or appropriately manicuring nails) [4]

AND

3 - Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine

Product Name: Brand Sporanox oral solution or generic itraconazole oral solution	
Diagnosis	Candidiasis (esophageal or oropharyngeal)
Approval Length	1 month [E, F]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPORANOX	ITRACONAZOLE ORAL SOLN 10 MG/ML	11407035002020	Brand
ITRACONAZOLE	ITRACONAZOLE ORAL SOLN 10 MG/ML	11407035002020	Generic

Approval Criteria

1 - One of the following:

1.1 Diagnosis of esophageal candidiasis

OR

1.2 Diagnosis of oropharyngeal candidiasis (OPC)

AND

2 - One of the following:

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

Product Name: Tolsura	
Approval Length	6 months [5, 10-12, B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TOLSURA	ITRACONAZOLE CAP 65 MG	11407035000113	Brand

Approval Criteria

1 - Diagnosis of one of the following fungal infections:

- Blastomycosis
- Histoplasmosis
- Aspergillosis

AND

2 - Trial and failure or intolerance to generic itraconazole capsules

Product Name: Brand Noxafil oral suspension or generic posaconazole oral solution	
Diagnosis	Oropharyngeal Candidiasis
Approval Length	1 Month [E]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Brand
POSACONAZOLE	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Generic

Approval Criteria

1 - Diagnosis of oropharyngeal candidiasis (OPC)

AND

2 - Patient is 13 years of age and older

AND

3 - One of the following:

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

Product Name: Brand Noxafil oral suspension or generic posaconazole oral solution	
Diagnosis	Oropharyngeal Candidiasis
Approval Length	1 Month [E]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Brand
POSACONAZOLE	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Generic

Approval Criteria

1 - Diagnosis of oropharyngeal candidiasis (OPC)

AND

2 - Patient is 13 years of age and older

AND

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

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet, Brand Noxafil oral suspension, generic posaconazole oral suspension, Noxafil PowderMix	
Diagnosis	Prophylaxis of systemic fungal infections
Approval Length	6 Months [B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Brand
POSACONAZOLE DR	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic
NOXAFIL	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Brand
NOXAFIL	POSACONAZOLE FOR DELAYED RELEASE SUSP PACKET 300 MG	11407060003020	Brand
POSACONAZOLE	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Generic

Approval Criteria

1 - Used as prophylaxis of invasive fungal infections caused by one of the following:

- Aspergillus
- Candida

AND

2 - One of the following:

2.1 For Noxafil (posaconazole) oral tablet, both of the following:

- Patient is 2 years of age and older
- Patient weighs greater than 40 kg

OR

2.2 For Noxafil oral suspension, patient is 13 years of age and older

OR

2.3 For Noxafil PowderMix, both of the following:

- Patient is 2 years of age and older
- Patient weighs 40 kg or less

AND

3 - One of the following:

3.1 Patient is at high risk of infections due to severe immunosuppression from one of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy

OR

3.2 Patient has a prior fungal infection requiring secondary prophylaxis [15, G]

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet, Brand Noxafil oral suspension, generic posaconazole oral suspension, Noxafil PowderMix	
Diagnosis	Prophylaxis of systemic fungal infections

Approval Length	6 Months [B-D]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Brand
POSACONAZOLE DR	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic
NOXAFIL	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Brand
NOXAFIL	POSACONAZOLE FOR DELAYED RELEASE SUSP PACKET 300 MG	11407060003020	Brand
POSACONAZOLE	POSACONAZOLE SUSP 40 MG/ML	11407060001820	Generic

Approval Criteria

1 - Used as prophylaxis of invasive fungal infections caused by one of the following:

- Aspergillus
- Candida

AND

2 - One of the following:

2.1 For Noxafil (posaconazole) oral tablet, both of the following:

- Patient is 2 years of age and older
- Patient weighs greater than 40kg

OR

2.2 For Noxafil oral suspension, patient is 13 years of age and older

OR

2.3 For Noxafil PowderMix, both of the following:

- Patient is 2 years of age and older

- Patient weighs 40 kg or less

AND

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

3.1 Patient is at high risk of infections due to severe immunosuppression from one of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy

OR

3.2 Patient has a prior fungal infection requiring secondary prophylaxis [15, G]

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet	
Diagnosis	Treatment of systemic fungal infections
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Brand
POSACONAZOLE DR	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic
POSACONAZOLE	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic

Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - Patient is 13 years of age and older

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet	
Diagnosis	Treatment of systemic fungal infections
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NOXAFIL	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Brand
POSACONAZOLE DR	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic
POSACONAZOLE	POSACONAZOLE TAB DELAYED RELEASE 100 MG	11407060000620	Generic

Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - Patient is 13 years of age and older

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Invasive Aspergillosis
Approval Length	6 Months [16, B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VORICONAZOLE	VORICONAZOLE TAB 50 MG	11407080000320	Generic
VFEND	VORICONAZOLE TAB 50 MG	11407080000320	Brand
VORICONAZOLE	VORICONAZOLE TAB 200 MG	11407080000340	Generic
VFEND	VORICONAZOLE TAB 200 MG	11407080000340	Brand
VORICONAZOLE	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Generic
VFEND	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Brand

Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - Patient is 2 years of age and older

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Serious Fungal Infections
Approval Length	6 Months [16, B-D]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VORICONAZOLE	VORICONAZOLE TAB 50 MG	11407080000320	Generic
VFEND	VORICONAZOLE TAB 50 MG	11407080000320	Brand
VORICONAZOLE	VORICONAZOLE TAB 200 MG	11407080000340	Generic
VFEND	VORICONAZOLE TAB 200 MG	11407080000340	Brand
VORICONAZOLE	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Generic
VFEND	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Brand

Approval Criteria

1 - Diagnosis of serious fungal infections (e.g., Scedosporium apiospermum, Fusarium species including Fusarium solani)

AND

2 - Patient is 2 years of age and older

AND

3 - Patient is intolerant of, or refractory to, other therapy (e.g., amphotericin B)

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Candidemia in non-neutropenic patients and other deep tissue Candida infections
Approval Length	1 Month [H, 16]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VORICONAZOLE	VORICONAZOLE TAB 50 MG	11407080000320	Generic
VFEND	VORICONAZOLE TAB 50 MG	11407080000320	Brand
VORICONAZOLE	VORICONAZOLE TAB 200 MG	11407080000340	Generic
VFEND	VORICONAZOLE TAB 200 MG	11407080000340	Brand
VORICONAZOLE	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Generic
VFEND	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Candidemia
- Deep tissue Candida infection (e.g., disseminated in skin, infection in abdomen, kidney, bladder wall, and wounds)

AND

2 - Patient is non-neutropenic

AND

3 - Patient is 2 years of age and older

AND

4 - One of the following:

- Trial and failure, contraindication or intolerance to fluconazole [I]
- Susceptibility results demonstrate resistance to fluconazole [K]

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Esophageal Candidiasis
Approval Length	1 Month [H, 16]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VORICONAZOLE	VORICONAZOLE TAB 50 MG	11407080000320	Generic
VFEND	VORICONAZOLE TAB 50 MG	11407080000320	Brand
VORICONAZOLE	VORICONAZOLE TAB 200 MG	11407080000340	Generic
VFEND	VORICONAZOLE TAB 200 MG	11407080000340	Brand
VORICONAZOLE	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Generic
VFEND	VORICONAZOLE FOR SUSP 40 MG/ML	11407080001920	Brand

Approval Criteria

1 - Diagnosis of esophageal candidiasis

AND

2 - Patient is 2 years of age and older

AND

3 - One of the following:

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

3 . Endnotes

A. Fingernail infections are usually reevaluated 18 weeks or longer after completion of therapy. Toenail infections are usually reevaluated 6-9 months after completion of therapy. [5] Indeed, considering that toenails can take 12 to 18 months to grow out, many clinicians consider that 1 year is too short to assess clinical effectiveness. [6] Reports of long-term follow-up of treated patients have recently been presented, suggesting that positive mycology at 12 and 24 weeks after commencement of therapy are poor prognostic signs and may indicate a need for retreatment or for a change of drug. [8]
B. The optimal duration of therapy for aspergillosis has not been defined. Most clinicians treat infections (pulmonary) until resolution or stabilization of clinical and radiographic manifestations. The IDSA recommends a minimal treatment period of 6 – 12 weeks in immunocompetent patients for invasive conditions. [11]
C. According to the IDSA guidelines for aspergillosis, duration of therapy for most conditions for aspergillosis has not been optimally defined. Most experts attempt to treat pulmonary infection until resolution or stabilization of all clinical and radiographic manifestations. Other factors include site of infection (e.g., osteomyelitis), level of immunosuppression, and extent of disease. Reversal of immunosuppression, if feasible, is important for a favorable outcome for invasive aspergillosis." [11]
D. According to the IDSA guidelines for the treatment of aspergillosis, both Amphotericin B and itraconazole are listed as second line treatment options for the treatment of invasive disease. [11]
E. For fluconazole-refractory OPC, either itraconazole or posaconazole for up to 28 days is recommended. For fluconazole-refractory esophageal candidiasis, itraconazole or voriconazole for 14 to 21 days is recommended. [3, 5]
F. Patients may be expected to relapse shortly after discontinuing therapy with Sporanox oral solution. Limited data on the safety of long-term use (> 6 months) of Sporanox Oral Solution are available at this time. [2]
G. NCCN recommends secondary prophylaxis with an appropriate antifungal agent in patients with prior chronic disseminated candidiasis or with invasive filamentous fungal infection during subsequent cycles of chemotherapy or HSCT. In patients with invasive aspergillosis before HSCT, antifungal therapy for more than a month and resolution of radiologic abnormalities correlate with a lower likelihood of post-transplant recurrence of infection. Secondary prophylaxis with a mold-active agent is advised for the entire period of immunosuppression. Secondary prophylaxis is generally administered for the duration of immunosuppression. Per recommendation from an infectious disease specialist, posaconazole is used for secondary prophylaxis of prior fungal infections. [15]
H. Voriconazole prescribing information states that for candidemia in non-neutropenic patients and other deep tissue Candida infections, patients should be treated for at least

14 days following resolution of symptoms or following last positive culture, whichever is long. For esophageal candidiasis, patients should be treated for a minimum of 14 days and for at least 7 days following resolution of symptoms. [16]

I. According to the 2016 IDSA guideline for candidemia in nonneutropenic patients, fluconazole, intravenous or oral, is an acceptable alternative to an echinocandin (e.g., caspofungin, micafungin, anidulafungin) in patients who are not critically ill and who are considered unlikely to have fluconazole-resistant Candida species. Voriconazole is effective for candidemia, however, offers little advantage over fluconazole as the initial therapy. [5]
J. According to the 2016 IDSA guideline for the treatment of esophageal candidiasis, oral fluconazole 200-400 mg for 14 to 21 days is strongly recommended (high-quality evidence). Intravenous fluconazole may be used in patients who cannot tolerate oral therapy. For fluconazole-refractory disease, voriconazole either intravenous or oral is recommended. [5]
K. Of the Candida species, C. krusei and C. glabrata are the two species with higher likelihood of fluconazole-resistance for serious candida infections due to widespread azole treatment. In these cases, voriconazole may be used as oral therapy in patients with infections due to C. krusei or fluconazole-resistant, voriconazole-susceptible C. glabrata infections. [5]

4 . References

1. Sporanox Capsules Prescribing Information. Janssen Pharmaceuticals, Inc.; Titusville, NJ. November 2023.
2. Sporanox Oral Solution Prescribing Information. Janssen Pharmaceuticals, Inc.; Titusville, NJ. November 2023.
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
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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. July 2023.
14. Noxafil Prescribing Information. Merck Sharp & Dohme Corp.; Whitehouse Station, NJ. October 2023.
15. Per Clinical Consultation with an Infectious Disease Specialist. January 24, 2014.
16. Voriconazole Tablet Prescribing Information. Ajanta Pharma Limited.; Bridgewater, NJ. November 2022.
17. Cresemba Prescribing Information. Astellas Pharma US., Inc. Northbrook, IL. December 2023.
18. Vfend Prescribing Information.Roerig. New York, NY. November 2022.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160817
Guideline Name	Banzel (rufinamide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Banzel (rufinamide) tablets and oral suspension
Lennox-Gastaut Syndrome (LGS) Indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in pediatric patients 1 year of age and older and in adults.

2 . Criteria

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

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BANZEL	RUFINAMIDE TAB 200 MG	72600065000320	Brand
BANZEL	RUFINAMIDE TAB 400 MG	72600065000330	Brand
BANZEL	RUFINAMIDE SUSP 40 MG/ML	72600065001820	Brand

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gaustaut Syndrome (LGS)

AND

2 - Used as adjunctive therapy

AND

3 - Patient is 1 year of age or older

AND

4 - One of the following:

- Trial of and inadequate response to, contraindication, or intolerance to ONE generic formulary anticonvulsant (e.g., topiramate, lamotrigine, valproate)
- For continuation of prior therapy if the patient is established on Brand Banzel

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: generic rufinamide	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RUFINAMIDE	RUFINAMIDE SUSP 40 MG/ML	72600065001820	Generic
RUFINAMIDE	RUFINAMIDE TAB 200 MG	72600065000320	Generic
RUFINAMIDE	RUFINAMIDE TAB 400 MG	72600065000330	Generic

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gaustaut Syndrome (LGS)

AND

2 - Used as adjunctive therapy

AND

3 - Patient is 1 year of age or older

AND

4 - One of the following:

- Trial of and inadequate response to, contraindication, or intolerance to ONE generic formulary anticonvulsant (e.g., topiramate, lamotrigine, valproate) other than generic rufinamide
- For continuation of prior therapy if the patient is established on generic rufinamide

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Brand Banzel, generic rufinamide

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

Product Name	Generic Name	GPI	Brand/Generic
BANZEL	RUFINAMIDE TAB 200 MG	72600065000320	Brand
BANZEL	RUFINAMIDE TAB 400 MG	72600065000330	Brand
BANZEL	RUFINAMIDE SUSP 40 MG/ML	72600065001820	Brand
RUFINAMIDE	RUFINAMIDE SUSP 40 MG/ML	72600065001820	Generic
RUFINAMIDE	RUFINAMIDE TAB 200 MG	72600065000320	Generic
RUFINAMIDE	RUFINAMIDE TAB 400 MG	72600065000330	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Banzel Prescribing Information. Eisai Inc. Woodcliff, NJ. April 2020.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160818
Guideline Name	Benlysta (belimumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Benlysta (belimumab IV), Benlysta (belimumab SC)
Systemic Lupus Erythematosus (SLE) Indicated for the treatment of patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in these situations. **Lupus Nephritis** Indicated for the treatment of patients aged 5 years and older with active lupus nephritis who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in these situations.

2 . Criteria

Product Name: Benlysta SC prefilled syringe	
Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/ML	9942201500E520	Brand

Approval Criteria

1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

2 - Autoantibody positive (i.e., anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL) [2, 3]

AND

3 - Patient is 18 years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [5]

AND

5 - Currently receiving at least one standard of care treatment for active SLE (e.g.,

antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [2, 3]

AND

6 - Prescribed by or in consultation with a rheumatologist

Product Name: Benlysta IV or Benlysta SC autoinjector	
Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENLYSTA	BELIMUMAB FOR IV SOLN 120 MG	99422015002120	Brand
BENLYSTA	BELIMUMAB FOR IV SOLN 400 MG	99422015002140	Brand
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/ML	9942201500D520	Brand

Approval Criteria

1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

2 - Autoantibody positive (i.e., anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL) [2, 3]

AND

3 - Patient is 5 years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [5]

AND

5 - Currently receiving at least one standard of care treatment for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [2, 3]

AND

6 - Prescribed by or in consultation with a rheumatologist

Product Name: Benlysta IV or Benlysta SC	
Diagnosis	Lupus nephritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENLYSTA	BELIMUMAB FOR IV SOLN 120 MG	99422015002120	Brand
BENLYSTA	BELIMUMAB FOR IV SOLN 400 MG	99422015002140	Brand
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/ML	9942201500D520	Brand
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/ML	9942201500E520	Brand

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - One of the following:

- For Benlysta IV, patient is 5 years of age or older
- For Benlysta SC, patient is 18 years of age or older

AND

3 - Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide) [1, 4]

AND

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

- Nephrologist
- Rheumatologist

Product Name: Benlysta IV or Benlysta SC	
Diagnosis	All indications listed above
Approval Length	6 months [2, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BENLYSTA	BELIMUMAB FOR IV SOLN 120 MG	99422015002120	Brand
BENLYSTA	BELIMUMAB FOR IV SOLN 400 MG	99422015002140	Brand
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/ML	9942201500D520	Brand
BENLYSTA	BELIMUMAB SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/ML	9942201500E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decrease or stabilization

of symptoms, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications)

3 . Endnotes

A. SLE is a disease that fluctuates. The undulating course of typical lupus patients requires frequent reassessment. A 6-month authorization period is reasonable. [2]

4 . References

1. Benlysta Prescribing Information. GlaxoSmithKline LLC. Philadelphia, PA. June 2024.
2. Per clinical consult with rheumatologist, October 4, 2017.
3. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus. Arthritis Rheum. 1999 Sep;42(9):1785-96.
4. American College of Rheumatology Guidelines for Screening, Case Definition, Treatment and Management of Lupus Nephritis. Arthritis Care Res (Hoboken). 2012 Jun; 64(6): 797-808.
5. Fanouriakis A, Kostopoulou M, Alunno A, et al. Ann Rheum Dis 2019;78:736–745.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160819
Guideline Name	Bevacizumab - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Avastin (bevacizumab)
Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab product-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer. **First-line Non-Squamous Non–Small Cell Lung Cancer (NSCLC)** Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel. **Recurrent Glioblastoma** Indicated for the treatment of recurrent glioblastoma in adults. **Metastatic Renal Cell Carcinoma (mRCC)** Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Cervical Cancer Indicated for the treatment of persistent, recurrent, or metastatic cervical cancer when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Hepatocellular Carcinoma Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

Drug Name: Mvasi (bevacizumab-awwb), Zirabev (bevacizumab-bvzr), Alymsys (bevacizumab-maly), Vegzelma (bevacizumab-adcd)

Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab product-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer.

First-line Non-Squamous Non–Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel.

Recurrent Glioblastoma Indicated for the treatment of recurrent glioblastoma in adults.

Metastatic Renal Cell Carcinoma (mRCC) Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Cervical Cancer Indicated for the treatment of persistent, recurrent, or metastatic cervical cancer when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received

no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Off Label Uses: **Hepatocellular Carcinoma** Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. [4, A]

2 . Criteria

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AVASTIN	BEVACIZUMAB IV SOLN 100 MG/4ML (FOR INFUSION)	21335020002025	Brand
AVASTIN	BEVACIZUMAB IV SOLN 400 MG/16ML (FOR INFUSION)	21335020002030	Brand
MVASI	BEVACIZUMAB-AWWB IV SOLN 100 MG/4ML (FOR INFUSION)	21335020202025	Brand
MVASI	BEVACIZUMAB-AWWB IV SOLN 400 MG/16ML (FOR INFUSION)	21335020202030	Brand
ZIRABEV	BEVACIZUMAB-BVZR IV SOLN 100 MG/4ML (FOR INFUSION)	21335020302025	Brand
ZIRABEV	BEVACIZUMAB-BVZR IV SOLN 400 MG/16ML (FOR INFUSION)	21335020302030	Brand
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 100 MG/4ML (FOR INFUSION)	21335020502025	Brand
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 400 MG/16ML (FOR INFUSION)	21335020502030	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 100 MG/4ML (FOR INFUSION)	21335020102025	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 400 MG/16ML (FOR INFUSION)	21335020102030	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

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

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

AND

2 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

2.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AVASTIN	BEVACIZUMAB IV SOLN 100 MG/4ML (FOR INFUSION)	21335020002025	Brand
AVASTIN	BEVACIZUMAB IV SOLN 400 MG/16ML (FOR INFUSION)	21335020002030	Brand
MVASI	BEVACIZUMAB-AWWB IV SOLN 100 MG/4ML (FOR INFUSION)	21335020202025	Brand
MVASI	BEVACIZUMAB-AWWB IV SOLN 400 MG/16ML (FOR INFUSION)	21335020202030	Brand
ZIRABEV	BEVACIZUMAB-BVZR IV SOLN 100 MG/4ML (FOR INFUSION)	21335020302025	Brand
ZIRABEV	BEVACIZUMAB-BVZR IV SOLN 400 MG/16ML (FOR INFUSION)	21335020302030	Brand
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 100 MG/4ML (FOR INFUSION)	21335020502025	Brand
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 400 MG/16ML (FOR INFUSION)	21335020502030	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 100 MG/4ML (FOR INFUSION)	21335020102025	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 400 MG/16ML (FOR INFUSION)	21335020102030	Brand

Approval Criteria

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

AND

2 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

2.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Alymsys, Vegzelma	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 100 MG/4ML (FOR INFUSION)	21335020502025	Brand
ALYMSYS	BEVACIZUMAB-MALY IV SOLN 400 MG/16ML (FOR INFUSION)	21335020502030	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 100 MG/4ML (FOR INFUSION)	21335020102025	Brand
VEGZELMA	BEVACIZUMAB-ADCD IV SOLN 400 MG/16ML (FOR INFUSION)	21335020102030	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

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

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

3 . Endnotes

A. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [4]

4 . References

1. Avastin Prescribing Information. Genentech Inc. South San Francisco, CA. September 2022.
2. Mvasi Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2023.
3. Zirabev Prescribing Information. Pfizer Inc. New York, NY. February 2023.
4. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed December 4, 2023.

5. Alymsys Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. April 2022.
6. Vegzelma Prescribing Information. Celltrion USA, Inc. Jersey City, NJ. February 2023.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-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

Prior Authorization Guideline

Guideline ID	GL-160820
Guideline Name	Bosulif (bosutinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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:

- Disease is in the chronic phase
- Patient is 1 year of age or older

AND

3 - One of the following:

- Trial and failure or intolerance to generic imatinib

- 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

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
11/19/2024	Bulk Copy. CM 11.19.24

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

1. Botox Prescribing Information. Allergan, Inc. Madison, NJ. November 2023.
2. AHFS Drug Information (2005) website. Available at: http://online.lexi.com/lco/action/doc/retrieve/docid/pdh_f/130028?searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3DBotox%26t%3Dname%26va%3DBotox. Accessed June 13, 2023.
3. DRUGDEX System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Accessed June 13, 2023.

4. Lowe NJ, Glaser DA, Eadie N, Daggett S, Kowalski JW, Lai PY. Botulinum toxin type A in the treatment of primary axillary hyperhidrosis: a 52-week multicenter double-blind, randomized, placebo-controlled study of efficacy and safety. J Am Acad Dermatol. 2007;56:604-611.
5. Naumann M, Lowe NJ. Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: randomised, parallel group, double blind, placebo controlled trial. BMJ 2001;323:596-9.
6. Vaezi MF, Pandolfino JE, Vela MF. American College of Gastroenterology Practice Parameter Committee. Diagnosis and management of achalasia. Am J Gastroenterol advance online publication, 23 July 2013.
7. Pasricha PJ, et al. Intrasphincteric botulinum toxin for the treatment of achalasia. N Engl J Med 1995;332:774-8.
8. American Society of Colon and Rectal Surgeons. Practice Parameters for the Management of Anal Fissures (3rd Revision). Dis Colon Rectum 2010; 53: 1110–1115.
9. Brisinda G, et al. A comparison of injections of botulinum toxin and topical nitroglycerin ointment for the treatment of chronic anal fissure. N Engl J Med 1999;341:65-9.
10. Ney JP, Difazio M, Sichani A, Monacci W, Foster L, Jabbari B. Treatment of chronic low back pain with successive injections of botulinum toxin A over 6 months: a prospective trial of 60 patients. Clin J Pain 2006;22(4):363-369.
11. MayoClinic. Back pain. Available at: www.mayoclinic.com. Accessed June 13, 2023.
12. Naumann M, So Y, Argoff CE et al. Assessment: botulinum neurotoxin in the treatment of autonomic disorder and pain (an evidence-based review): report of the Therapeutics and Assessment Subcommittee of the American Academy of Neurology. Neurology 2008;70:1707-1714.
13. Aurora SK, Dodick DW, Turkel CC, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 1 trial. Cephalagia. 2010;30:793-803.
14. Diener HC, Dodick DW, Aurora SK, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. Cephalagia. 2010;30:804-814.
15. Dodick DW, Turkel CC, DeGryse RE, et al. OnabotulinumtoxinA for treatment of chronic migraine: pooled results from the double-blind, randomized, placebo-controlled phases of the PREEMPT clinical program. Headache. 2010;50:921-936.
16. Per clinical consultation with neurologist, January 7, 2011.
17. Silberstein SD, Holland S, Freitag F, et al; Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology 2012 Apr 24;78(17):1337-45.
18. Loder E, Burch R, Rizzoli P.The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A Summary and Comparison With Other Recent Clinical Practice Guidelines. Headache 2012;52:930-945.
19. Per clinical consultation with neurologist, July 20, 2015.
20. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition (beta version). Cephalalgia. 2013; 33: 629-808.
21. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26.
22. Per Clinical Consultation with a Neurologist. January 24th, 2018.

23. National Institute for Health and Care Excellence. Management of migraine (with or without aura). April 17th, 2018. Available at: https://pathways.nice.org.uk/pathways/headaches/management-of-migraine-with-or-without-aura#path=view%3A/pathways/headaches/management-of-migraine-with-or-without-aura.xml&content=view-node%3Anodes-prophylactic-treatment. Accessed August 14, 2020.
24. Botox Cosmetic Prescribing Information. Allergan, Inc. Irvine, CA. November 2023.

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-160821
Guideline Name	Cablivi (caplacizumab-yhdp)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cablivi (caplacizumab-yhdp)
Acquired Thrombotic Thrombocytopenic Purpura (aTTP) Indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

2 . Criteria

Product Name: Cablivi	
Diagnosis	Acquired Thrombotic Thrombocytopenic Purpura (aTTP)
Approval Length	3 Months [A]

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABLIVI	CAPLACIZUMAB-YHDP FOR INJ KIT 11 MG	85151020806420	Brand

Approval Criteria

1 - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)

AND

2 - First dose was/will be administered by a healthcare provider as a bolus intravenous injection

AND

3 - Used in combination with immunosuppressive therapy (e.g., rituximab, glucocorticoids) [3]

AND

4 - One of the following:

4.1 Used in combination with plasma exchange

OR

4.2 Both of the following:

- Patient has completed plasma exchange
- Less than 59 days have or will have elapsed beyond the last plasma exchange [B]

AND

5 - Prescribed by or in consultation with a hematologist or oncologist[2]

3 . Endnotes

A. Three month approval duration, based on package insert stating longest therapy in trial was 77 days.
B. Per package insert, after the plasma exchange period can use injection once daily for 30 days beyond the last plasma exchange and after the initial treatment course, if signs of persistent underlying disease are present treatment can be extended for a maximum of 28 days, totaling 58 days of therapy after last plasma exchange.

4 . References

1. Cablivi Prescribing Information. Cambridge, MA. Genzyme Corporation. April 2023
2. Understanding TTP. https://www.understandingttp.com/patient/ttp-treatment/#overview-of-treatment. Accessed January 28, 2021.
3. FDA News Release: FDA approves first therapy for the treatment of adult patients with a rare blood clotting disorder. U.S. Food and Drug Administration; February 6, 2019. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630851.htm. Accessed January 28, 2021.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160822
Guideline Name	Cabometyx (cabozantinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cabometyx (cabozantinib) tablets
Renal cell carcinoma (RCC) Indicated for the treatment of patients with advanced renal cell carcinoma (RCC). **Renal cell carcinoma (RCC)** Indicated, in combination with nivolumab, for the first-line treatment of patients with advanced RCC. **Hepatocellular Carcinoma (HCC)** Indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. **Differentiated Thyroid Cancer** Indicated for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.

2 . Criteria

Product Name: Cabometyx	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABOMETYX	CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)	21533010100320	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)	21533010100330	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)	21533010100340	Brand

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Cabometyx	
Diagnosis	Hepatocellular Carcinoma (HCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABOMETYX	CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)	21533010100320	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)	21533010100330	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)	21533010100340	Brand

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma (HCC)

AND

2 - Trial and failure, contraindication, or intolerance to Nexavar (sorafenib tosylate)*

Notes	*Criterion is part of the FDA-approved label. If patient meets criteria a bove, please approve at GPI-12.

Product Name: Cabometyx	
Diagnosis	Differentiated Thyroid Cancer (DTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABOMETYX	CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)	21533010100320	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)	21533010100330	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)	21533010100340	Brand

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC) [A, 5]

AND

2 - Patient is 12 years of age or older

AND

3 - Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib])*

AND

4 - Disease or patient is refractory to radioactive iodine treatment or ineligible

Notes	*Criterion is part of the FDA-approved label. If patient meets criteria a bove, please approve at GPI-12.

Product Name: Cabometyx	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABOMETYX	CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)	21533010100320	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)	21533010100330	Brand
CABOMETYX	CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)	21533010100340	Brand

Approval Criteria

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

Notes	If patient meets criteria above, please approve at GPI-12.

3 . Endnotes

A. Differentiated thyroid carcinomas are broadly categorized as papillary thyroid carcinoma (PTC), follicular cancer (FTC), and Hurthle cell carcinoma (HCTC). [3]

4 . References

1. Cabometyx Prescribing Information. Exelixis, Inc. Alameda, CA. September 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 6, 2024.
3. Patel K, Yip L, Lubitz C et al. The American Association of Endocrine Surgeons Guidelines for the Definitive Surgical Management of Thyroid Disease in Adults. Ann Surg. 2020;271(3):e21-e93.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160823
Guideline Name	Cabotegravir Containing Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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.

Drug Name: Apretude (cabotegravir) Injection

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 prior to initiating Apretude (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

2 . Criteria

Product Name: Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CABENUVA	CABOTEGRAVIR 400 MG/2ML & RILPIVIRINE 600 MG/2ML IM SUSP ER	1210990225G120	Brand
CABENUVA	CABOTEGRAVIR 600 MG/3ML & RILPIVIRINE 900 MG/3ML IM SUSP ER	1210990225G130	Brand
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - For continuation of prior therapy

Notes	*If patient meets criteria above, please approve both Vocabria and Ca benuva at GPI list “CABOTEGRPA”.

Product Name: Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection

Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CABENUVA	CABOTEGRAVIR 400 MG/2ML & RILPIVIRINE 600 MG/2ML IM SUSP ER	1210990225G120	Brand
CABENUVA	CABOTEGRAVIR 600 MG/3ML & RILPIVIRINE 900 MG/3ML IM SUSP ER	1210990225G130	Brand
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 70-day gap in therapy [A]

Notes	*If patient meets criteria above, please approve both Vocabria and Cabenuva at GPI list “CABOTEGRPA”.

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand
APRETUDE	CABOTEGRAVIR IM EXTENDED RELEASE SUSP 600 MG/3ML	1210301000G120	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 or Apretude:

- 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 both Vocabria and A pretude at GPI list “APRETUDEPA”

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand
APRETUDE	CABOTEGRAVIR IM EXTENDED RELEASE SUSP 600 MG/3ML	1210301000G120	Brand

Approval Criteria

1 - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude

AND

2 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to each maintenance injection of Apretude for HIV PrEP:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

Notes	**If patient meets criteria above, please approve both Vocabria and A pretude at GPI list “APRETUDEPA”

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand
APRETUDE	CABOTEGRAVIR IM EXTENDED RELEASE SUSP 600 MG/3ML	1210301000G120	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 or Apretude:

- 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 both Vocabria and A pretude at GPI list “APRETUDEPA”

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VOCABRIA	CABOTEGRAVIR SODIUM TAB 30 MG	12103010200320	Brand
APRETUDE	CABOTEGRAVIR IM EXTENDED RELEASE SUSP 600 MG/3ML	1210301000G120	Brand

Approval Criteria

1 - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude

AND

2 - Submission of medical records (e.g., chart notes) confirming documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to each maintenance injection of Apretude for HIV PrEP:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

Notes	**If patient meets criteria above, please approve both Vocabria and A pretude 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.

3. Apretude Prescribing information. ViiV Healthcare Company. Research Triangle Park, NC. December 2023.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160824
Guideline Name	Cannabinoids
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Marinol (dronabinol) capsule, Syndros (dronabinol) oral solution
Chemotherapy-induced nausea and vomiting Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. **Anorexia in patients with AIDS** Indicated in adults for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS)

2 . Criteria

Product Name: Brand Marinol

Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MARINOL	DRONABINOL CAP 2.5 MG	50300030000110	Brand
MARINOL	DRONABINOL CAP 5 MG	50300030000115	Brand
MARINOL	DRONABINOL CAP 10 MG	50300030000120	Brand

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Trial and failure, contraindication, or intolerance to formulary generic dronabinol capsules*

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes	*This product may require prior authorization.

Product Name: Generic dronabinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DRONABINOL	DRONABINOL CAP 2.5 MG	50300030000110	Generic
DRONABINOL	DRONABINOL CAP 5 MG	50300030000115	Generic
DRONABINOL	DRONABINOL CAP 10 MG	50300030000120	Generic

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Syndros	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNDROS	DRONABINOL SOLN 5 MG/ML	0300030002020	Brand

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - One of the following:

- Trial and failure or intolerance to formulary generic dronabinol capsules*
- Patient is unable to swallow capsules

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes	*This product may require prior authorization.

Product Name: Brand Marinol

Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MARINOL	DRONABINOL CAP 2.5 MG	50300030000110	Brand
MARINOL	DRONABINOL CAP 5 MG	50300030000115	Brand
MARINOL	DRONABINOL CAP 10 MG	50300030000120	Brand

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

AND

4 - Trial and failure or intolerance to formulary generic dronabinol capsules*

Notes	*This product may require prior authorization.

Product Name: Generic dronabinol	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DRONABINOL	DRONABINOL CAP 2.5 MG	50300030000110	Generic
DRONABINOL	DRONABINOL CAP 5 MG	50300030000115	Generic
DRONABINOL	DRONABINOL CAP 10 MG	50300030000120	Generic

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

Product Name: Syndros

Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNDROS	DRONABINOL SOLN 5 MG/ML	50300030002020	Brand

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-4, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

AND

4 - One of the following:

- Trial and failure or intolerance to formulary generic dronabinol capsules*
- Patient is unable to swallow capsules

Notes	*This product may require prior authorization.

3 . Endnotes

A. Per NCCN, cannabinoids are agents that can be used for breakthrough treatment. Other agents used for breakthrough treatment include: phenothiazines (prochlorperazine, promethazine), prokinetic agents (metoclopramide), antipsychotic agents (haloperidol, olanzapine), corticosteroids (dexamethasone), benzodiazepines (lorazepam), and 5-HT3 receptor antagonists (dolasetron, granisetron, ondansetron). [1]

4 . References

1. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Antiemesis v.1.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed March 9, 2022.
2. Marinol prescribing information. Patheon Softgels, Inc. High Point, NC. March 2021.
3. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed August 22, 2016.
4. American Geriatrics Society 2019 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;00:1-21.
5. Pascual Lopez A, Roque i Figuls M, Urrutia Cuchi G, et al. Systematic review of megestrol acetate in the treatment of anorexia-cachexia syndrome. J Pain Symptom Manage 2004;27:360-369.
6. Per clinical consult with HIV specialist, February 4, 2013.
7. Syndros prescribing information. Benuvia Therapeutics, Inc. Chandler, AZ. January 2021.
8. Williams B, Waters D, Parker K. Evaluation and Treatment of Weight Loss in Adults with HIV Disease. Am Fam Physician. 1999;60(3):843-854.
9. Grinspoon S, Mulligan K; Department of Health and Human Services Working Group on the Prevention and Treatment of Wasting and Weight Loss. Weight loss and wasting in patients infected with human immunodeficiency virus. Clin Infect Dis. 2003;36(Suppl 2):S69-78.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160825
Guideline Name	Caprelsa (vandetanib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Caprelsa (vandetanib)
Medullary Thyroid Cancer (MTC) Indicated for the treatment of symptomatic or progressive MTC in patients with unresectable locally advanced or metastatic disease. Use Caprelsa in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of Caprelsa.

2 . Criteria

Product Name: Caprelsa	
Approval Length	12 Months
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CAPRELSA	VANDETANIB TAB 100 MG	21533085000320	Brand
CAPRELSA	VANDETANIB TAB 300 MG	21533085000340	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Metastatic medullary thyroid cancer (MTC)
- Unresectable locally advanced MTC

AND

2 - One of the following:

- Patient has symptomatic disease
- Patient has progressive disease

Product Name: Caprelsa	
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CAPRELSA	VANDETANIB TAB 100 MG	21533085000320	Brand
CAPRELSA	VANDETANIB TAB 300 MG	21533085000340	Brand

Approval Criteria

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

3 . References

1. Caprelsa prescribing information. Genzyme Corporation. Cambridge, MA. April 2024.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160826
Guideline Name	Cayston (aztreonam for inhalation solution) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cayston (aztreonam for inhalation solution)
Cystic Fibrosis Indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with Pseudomonas aeruginosa. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV1 less than 25% or greater than 75% predicted, or patients colonized with Burkholderia cepacia. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cayston and other antibacterial drugs, Cayston should be used only to treat patients with CF known to have Pseudomonas aeruginosa in the lungs.

2 . Criteria

Product Name: Cayston

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

Product Name	Generic Name	GPI	Brand/Generic
CAYSTON	AZTREONAM LYSINE FOR INHAL SOLN 75 MG (BASE EQUIVALENT)	16140010402120	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis

AND

2 - Patient has evidence of Pseudomonas aeruginosa in the lungs

AND

3 - Patient is seven years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to TWO of the following:

- Bethkis* (tobramycin [300 mg/4 ml] inhalation solution)
- TOBI* (tobramycin [300 mg/5 ml] inhalation solution)
- Tobi Podhaler (tobramycin capsule)

Notes	*NOTE: Step Therapy (ST) requirements may apply for brand Bethkis and brand TOBI

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

Product Name	Generic Name	GPI	Brand/Generic
CAYSTON	AZTREONAM LYSINE FOR INHAL SOLN 75 MG (BASE EQUIVALENT)	16140010402120	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis

AND

2 - Patient has evidence of Pseudomonas aeruginosa in the lungs

AND

3 - Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

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

Product Name	Generic Name	GPI	Brand/Generic
CAYSTON	AZTREONAM LYSINE FOR INHAL SOLN 75 MG (BASE EQUIVALENT)	16140010402120	Brand

Approval Criteria

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

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has evidence of Pseudomonas aeruginosa in the lungs

AND

3 - Patient is seven years of age or older

AND

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

- generic tobramycin [300 mg/4 ml] inhalation solution
- generic tobramycin [300 mg/5 ml] inhalation solution
- Tobi Podhaler (tobramycin capsule)

3 . References

1. Cayston Prescribing Information. Gilead Sciences, Inc. Foster City, CA. November 2019.
2. Retsch-Bogart GZ, Quittner AL, Gibson RL, et al. Efficacy and safety of inhaled aztreonam lysine for airway Pseudomonas in cystic fibrosis. Chest. 2009;135:1223-32.
3. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic Fibrosis Foundation Pulmonary Guideline. Pharmacologic approaches to prevention and eradication of initial Pseudomonas aeruginosa infection. Ann Am Thorac Soc. 2014;11(10):1640-50.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160827
Guideline Name	CGRP Inhibitors - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), Vyepti (eptinezumab-jjmr); Qulipta (atogepant)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.
Drug Name: Emgality (galcanezumab-gnlm)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults. **Episodic Cluster Headache** Indicated for the treatment of episodic cluster headache in adults.
Drug Name: Nurtec ODT (rimegepant)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults.

Preventive Treatment of Episodic Migraine Indicated for the preventive treatment of episodic migraine in adults.
Drug Name: Ubrelvy (ubrogepant), Zavzpret (zavegepant)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Ubrelvy AND Zavzpret are not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name: Aimovig or Ajovy	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AIMOVIG	ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-INJECTOR 70 MG/ML	6770202010D520	Brand
AIMOVIG	ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML	6770202010D540	Brand
AJOVY	FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN PREF SYR 225 MG/1.5ML	6770203020E520	Brand
AJOVY	FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN AUTO-INJ 225 MG/1.5ML	6770203020D520	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has greater than or equal to 4 migraine days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name: Aimovig or Ajovy	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AJOVY	FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN PREF SYR 225 MG/1.5ML	6770203020E520	Brand
AIMOVIG	ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-INJECTOR 70 MG/ML	6770202010D520	Brand
AIMOVIG	ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML	6770202010D540	Brand
AJOVY	FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN AUTO-INJ 225 MG/1.5ML	6770203020D520	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines)

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN AUTO-INJECTOR 120 MG/ML	6770203530D520	Brand
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 120 MG/ML	6770203530E520	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has greater than or equal to 4 migraine days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

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

- Aimovig
- Ajovy

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Notes	*QL Override for Emgality (For new starts only): For migraine, please enter 2 PAs with the same start date as follows: First PA: Approve two pens or syringes per 30 days for 1 month with a fill count of 2 (Loading dose has a MDD of 0.067); Second PA: Approve one pen or syringe per 30 days (no overrides needed) for 6 months. (Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen/syringe per 30 days)

Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN AUTO-INJECTOR 120 MG/ML	6770203530D520	Brand
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 120 MG/ML	6770203530E520	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines)

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

AND

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

- Aimovig
- Ajovy

Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 months [E]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN AUTO-INJECTOR 120 MG/ML	6770203530D520	Brand
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 120 MG/ML	6770203530E520	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.1.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 4 migraine days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic migraines

AND

1.2.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Both of the following:

4.1 Submission of medical records (e.g., chart notes) confirming a history of failure after at least a 12 week trial to BOTH of the following (unless there is a contraindication or intolerance):

- Aimovig
- Ajovy

AND

4.2 Submission of medical records (e.g., chart notes) confirming a history of failure after at least an 8 week trial to ONE of the following (unless there is a contraindication or intolerance):

- Nurtec
- Qulipta

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Notes	*QL Override for Emgality (For new starts only): For migraine, please enter 2 PAs with the same start date as follows: First PA: Approve two pens or syringes per 30 days for 1 month with a fill count of 2 (Loading dose has a MDD of 0.066); Second PA: Approve one pen or syringe per 30 days (no overrides needed) for 6 months. (Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen/syringe per 30 days)

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has greater than or equal to 4 migraine days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a qua lity limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.

Product Name: Nurtec ODT

Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines)

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Notes	Nurtec ODT: For use for preventive treatment of migraine, please ente r a quality limit override of #16 tablets per 30 days (MDD, 0.54) for 12 months.

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Both of the following:

1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 4 migraine days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a qua lity limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.

Product Name: Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QULIPTA	ATOGEPANT TAB 10 MG	67701010000310	Brand
QULIPTA	ATOGEPANT TAB 30 MG	67701010000320	Brand
QULIPTA	ATOGEPANT TAB 60 MG	67701010000330	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has greater than or equal to 4 migraine days per month [28]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name: Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QULIPTA	ATOGEPANT TAB 10 MG	67701010000310	Brand
QULIPTA	ATOGEPANT TAB 30 MG	67701010000320	Brand
QULIPTA	ATOGEPANT TAB 60 MG	67701010000330	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed)

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name: Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
QULIPTA	ATOGEPANT TAB 10 MG	67701010000310	Brand
QULIPTA	ATOGEPANT TAB 30 MG	67701010000320	Brand
QULIPTA	ATOGEPANT TAB 60 MG	67701010000330	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.1.2 Submission of medical records (e.g., chart notes) confirming the patient greater than or equal to 4 migraine days per month [28]

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic migraines

AND

1.2.2 Submission of medical records (e.g., chart notes) confirming a patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Submission of medical records (e.g., chart notes) confirming a medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventive treatments to migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name: Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYEPTI	EPTINEZUMAB-JJMR IV SOLN 100 MG/ML	67702015202020	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has greater than or equal to 4 migraine days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventative treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

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

- Aimovig

- Ajovy

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name: Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYEPTI	EPTINEZUMAB-JJMR IV SOLN 100 MG/ML	67702015202020	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines)

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

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

- Aimovig
- Ajovy

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name: Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VYEPTI	EPTINEZUMAB-JJMR IV SOLN 100 MG/ML	67702015202020	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.1.2 Submission of medical records (e.g., chart notes) the patient has greater than or equal to 4 migraine days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic migraines

AND

1.2.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 8 migraine days per month [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following preventative treatments for migraine from different mechanisms of action [D, E, F, G, 10]:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

4 - Both of the following:

4.1 Submission of medical records (e.g., chart notes) confirming a history of failure after at least a 12 week trial to BOTH of the following (unless there is a contraindication or intolerance):

- Aimovig
- Ajovy

AND

4.2 Submission of medical records (e.g., chart notes) confirming a history of failure after at least an 8 week trial to ONE of the following (unless there is a contraindication or intolerance):

- Nurtec ODT
- Qulipta

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the PREVENTIVE treatment of migraines

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 100 MG/ML	6770203530E515	Brand

Approval Criteria

1 - Diagnosis of episodic cluster headache

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months [21]

AND

3 - Patient is 18 years of age or older [I]

AND

4 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMGALITY	GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 100 MG/ML	6770203530E515	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed)

AND

2 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, one of the following [D, 24]:

5.1 Patient must be currently treated with ONE preventive treatment for migraine from the following:

- Elavil [amitriptyline]
- Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium]
- Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan

- Lisinopril

OR

5.2 Patient has a history of failure (after at least a two month trial), contraindication or intolerance to ONE preventative treatment for migraine from the following:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - Paid claims or submission of medical records (e.g., chart notes) one of the following: [D, 24]

5.1 Patient must be currently treated with ONE preventive treatment for migraine from the following:

- Elavil [amitriptyline]
- Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium]
- Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

OR

5.2 Patient has a history of failure (after at least a two month trial), contraindication, or intolerance to THREE preventative treatments for migraine from the following different mechanisms of action:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UBRELVY	UBROGEPANT TAB 50 MG	67701080000320	Brand
UBRELVY	UBROGEPANT TAB 100 MG	67701080000340	Brand

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, one of the following [D, 24]:

5.1 Patient must be currently treated with ONE preventive treatment for migraine from the following:

- Elavil [amitriptyline]
- Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium]
- Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

OR

5.2 Patient has a history of failure (after at least a two month trial), contraindication or intolerance to ONE preventative treatment for migraine from the following:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UBRELVY	UBROGEPANT TAB 50 MG	67701080000320	Brand
UBRELVY	UBROGEPANT TAB 100 MG	67701080000340	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Will not be used for preventive treatment of migraine

AND

3 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
UBRELVY	UBROGEPANT TAB 50 MG	67701080000320	Brand
UBRELVY	UBROGEPANT TAB 100 MG	67701080000340	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the ACUTE treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, one of the following: [D, 24]

5.1 Patient must be currently treated with ONE preventive treatment for migraine from the following:

- Elavil [amitriptyline]
- Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium]
- Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

OR

5.2 Patient has a history of failure (after at least a two month trial), contraindication, or intolerance to THREE preventative treatments for migraine from the following:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name: Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZAVZPRET	ZAVEGEPANT HCL NASAL SPRAY 10 MG/ACT	67701090202020	Brand

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, one of the following: [D, 24]

5.1 Patient must be currently treated with ONE preventive treatment for migraine from the following:

- Elavil [amitriptyline]
- Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium]
- Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan

- Lisinopril

OR

5.2 Patient has a history of failure (after at least a two month trial), contraindication, or intolerance to ONE preventative treatment for migraine from the following:

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, or metoprolol
- Candesartan
- Lisinopril

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

Product Name: Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZAVZPRET	ZAVEGEPANT HCL NASAL SPRAY 10 MG/ACT	67701090202020	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Will not be used for preventive treatment of migraine

AND

3 - Medication will not be used in combination with another CGRP inhibitor for the ACUTE treatment of migraines

3 . Endnotes

A. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [11]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.
B. While every patient with chronic migraine should receive preventive therapy, not every patient with episodic migraine needs prevention [12]. Appropriate candidates for preventative treatment include those with at least 4 days per month of headache-related disability.
C. The phase 3 inclusion criteria for the erenumab (LIBERTY, STRIVE, ARISE) and galcanezumab (EVOLVE-1, EVOLVE-2) pivotal trials in episodic migraine required that patients had 4 to 14 migraine days per month [3-9]. The LEADER trial evaluated patients who had failed two to four prior preventive migraine treatments (PMTs). At the start of the trial, 38.6%, 37.8%, and 22.8% of patients had failed two, three, and four prior PMTs, respectively [2].
D. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan [16, 24].
E. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [15]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
F. The OptumRx clinical team consulted with a neurologist on the prospective review of the CGPR Inhibitors [14]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more on patient specific factors. Also, he felt that this agent will most likely fall into a similar place in therapy as Botox (onabotulinumtoxin A).
G. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [13].

H. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [11]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
I. The safety and effectiveness in pediatric patients has not been established [1, 17-19, 20, 22, 29].
J. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS). [25]

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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160828
Guideline Name	Cholbam (cholic acid)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cholbam (cholic acid)
Bile acid synthesis disorders due to single enzyme defects (SEDs) Indicated for the treatment of bile acid synthesis disorders due to single enzyme defects (SEDs). Limitation of use: The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders have not been established. **Peroxisomal disorders including Zellweger spectrum disorders** Indicated for adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption. Limitation of use: The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders have not been established.

2 . Criteria

Product Name: Cholbam	
Diagnosis	Bile acid synthesis disorders
Approval Length	4 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHOLBAM	CHOLIC ACID CAP 50 MG	52700025000120	Brand
CHOLBAM	CHOLIC ACID CAP 250 MG	52700025000140	Brand

Approval Criteria

1 - Diagnosis of a bile acid synthesis disorder due to a single enzyme defect based on one of the following: [1-6,8,A,B]

- An abnormal urinary bile acid analysis by mass spectrometry
- Molecular genetic testing consistent with the diagnosis

AND

2 - Prescribed by one of the following: [2,7,E]

- Hepatologist
- Medical geneticist
- Pediatric gastroenterologist
- Other specialist that treats inborn errors of metabolism

Product Name: Cholbam	
Diagnosis	Peroxisomal disorders
Approval Length	4 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHOLBAM	CHOLIC ACID CAP 50 MG	52700025000120	Brand
CHOLBAM	CHOLIC ACID CAP 250 MG	52700025000140	Brand

Approval Criteria

1 - Diagnosis of a peroxisomal disorder based on one of the following: [2-5,8,C,D]

- An abnormal urinary bile acid analysis by mass spectrometry
- Molecular genetic testing consistent with the diagnosis

AND

2 - Patient exhibits manifestations of at least one of the following: [2-3]

- Liver disease (e.g., jaundice, elevated serum transaminases)
- Steatorrhea
- Complications from decreased fat-soluble vitamin absorption (e.g., poor growth)

AND

3 - Prescribed by one of the following: [2,7,E]

- Hepatologist
- Medical geneticist
- Pediatric gastroenterologist
- Other specialist that treats inborn errors of metabolism

AND

4 - Used as adjunctive treatment [2-3]

Product Name: Cholbam	
Diagnosis	Bile acid synthesis disorders or Peroxisomal disorders
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CHOLBAM	CHOLIC ACID CAP 50 MG	52700025000120	Brand
CHOLBAM	CHOLIC ACID CAP 250 MG	52700025000140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT])

3 . Endnotes

A. Congenital deficiencies in the enzymes responsible for catalyzing key reactions in the synthesis of primary bile acids cholic acid and chenodeoxycholic acid are referred to as bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs). [1] 3 beta-hydroxy-D5-C27-steroid oxidoreductase deficiency (3 beta-HSD) and D4-3-oxosteroid 5 beta-reductase deficiency (AKR1D1 or D4-3-oxo-R), inherited by an autosomal recessive mode, are the most frequent inborn errors of primary bile acid synthesis causing early cirrhosis and liver failure. [6] See Background Table 1 for a list of known bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs). [1]
B. 2- (or alpha-) methylacyl-CoA racemase (AMACR) deficiency is a deficiency of a single peroxisomal enzyme that may manifest secondary abnormalities of bile acid synthesis; it may thus technically be considered a BASD, as well as, a peroxisomal disorder (PD). [2-5]
C. The spectrum of diseases referred to as peroxisomal disorders (PDs) involve defects in later steps of the bile acid synthetic pathway, such as impaired side-chain oxidation; [3] PDs are therefore classified as either disorders of peroxisome biogenesis (eg, Zellweger syndrome) or deficiencies of a single peroxisomal enzyme (eg, 2- (or alpha-)methylacyl-CoA racemase [AMACR] deficiency). [3] See Background Table 2 for a list of known PDs. [5]
D. Zellweger syndrome, infantile Refsum disease, neonatal adrenoleukodystrophy and rhizomelic chondrodysplasia punctata type 1 (RCDP1) are examples of defective biogenesis in which peroxisomes are absent. [4-5] The first 3 disorders are thought to represent a clinical continuum, referred to as Zellweger spectrum disorders (ZSD), with Zellweger syndrome the most severe, infantile Refsum disease the mildest, and neonatal adrenoleukodystrophy intermediate in severity. [5]
E. As per the prescribing information [2], treatment with Cholbam should be initiated and monitored by an experienced hepatologist or pediatric gastroenterologist. At the University of California, San Francisco, medical geneticists see patients with PDs, while specialists in pediatric gastroenterology see patients with BASDs. [7]

F. Cholbam should be discontinued if liver function does not improve within 3 months of starting treatment. [2] An additional month is added to the initial authorization duration to allow for patient follow-up with the provider.

4 . References

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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160829
Guideline Name	Cibinqo (abrocitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 both of the following FDA-approved atopic dermatitis therapies:

- Adbry (tralokinumab-ldrm)
- 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 - Patient demonstrates a positive clinical response to therapy as evidenced by at least ONE of the following:

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

AND

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

Notes	*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
	Amcinonide	Cream, lotion, ointment	0.1

High Potency	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05

	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

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

5 . References

1. Cibinqo Prescribing Information. Pfizer Labs. New York, NY. December 2023.
2. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023; Epub ahead of print.
3. European Task Force on Atopic Dermatitis. Severity scoring of atopic dermatitis: the SCORAD index. Consensus report of the European Task Force on atopic dermatitis. Dermatology. 1993; 186:23-31.
4. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. Lancet 2017; 389(10086)(suppl):2287-2303.
5. Oranje AP. Practical issues on interpretation of scoring atopic dermatitis: SCORAD index, objective SCORAD, patient-oriented SCORAD and three-item severity score. Curr Probl Dermatol. 2011; 41:149-55.

6 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160830
Guideline Name	Cimzia (certolizumab pegol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cimzia (certolizumab pegol)
Rheumatoid Arthritis (RA) Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis. **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 10F860	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	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 [4, 5]:

- 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	5250502010F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	5250502010F860	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, 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: 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	5250502010F840	Brand

CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F860	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

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: 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	52505020 10F840	Brand

CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	5250502010F860	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, 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: 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	5250502010F860	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [8]:

- 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 [9]:

- 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	5250502010F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	5250502010F860	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, 8]:

- 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 10F860	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	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 [7]

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	5250502010F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	5250502010F860	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, 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: 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	5250502010F860	Brand
CIMZIA	CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG	52505020106420	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, 7]

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 [7]

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	5250502010F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	5250502010F860	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, 7]:

- 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	52505020 10F840	Brand
CIMZIA STARTER KIT	CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML	52505020 10F860	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

AND

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

- Frequent diarrhea and abdominal pain
- At least 10% weight loss

- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [2, 3]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

4 - 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	5250502010F860	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]:

- 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. December 2022.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
3. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.
4. 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.
5. 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.
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. 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.
9. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160831
Guideline Name	Clinical Duplicates Program
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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, 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			

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160832
Guideline Name	Colony-Stimulating Factors (CSFs) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Fulphila (pegfilgrastim-jmdb, G-CSF), Fylnetra (pegfilgrastim-pbbk), Nyvepria (pegfilgrastim-apgf, G-CSF), Stimufend (pegfilgrastim-fpgk), Ziextenzo (pegfilgrastim-bmez, G-CSF)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Pegfilgrastim is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. **Off Label Uses: Hematopoietic Subsyndrome of Acute Radiation Syndrome** To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M] **Treatment of High-Risk Febrile Neutropenia (FN)** For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]

Drug Name: Granix (tbo-filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to reduce the duration of severe neutropenia in adult and pediatric patients 1 month and older with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [16]

Drug Name: Leukine (sargramostim, GM-CSF)

Acute Myeloid Leukemia (AML) Following Induction Chemotherapy Indicated to shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML).

Autologous Peripheral Blood Progenitor Cell Mobilization and Collection Indicated in adult patients with cancer undergoing autologous hematopoietic stem cell transplantation for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis.

Autologous Peripheral Blood Progenitor Cell and Bone Marrow Transplantation Indicated for the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric patients 2 years of age and older with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's lymphoma (HL).

Allogeneic Bone Marrow Transplantation (BMT) Indicated for the acceleration of myeloid reconstitution in adult and pediatric patients 2 years of age and older undergoing allogeneic bone marrow transplantation from HLA-matched related donors.

Allogeneic or Autologous Bone Marrow Transplantation: Treatment of Delayed Neutrophil Recovery or Graft Failure Indicated for the treatment of adult and pediatric patients 2 years and older who have undergone allogeneic or autologous bone marrow transplantation in whom neutrophil recovery is delayed or failed.

Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS) Indicated to increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

Off Label Uses: Febrile Neutropenia (FN), Prophylaxis Has been used in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever [11]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia [37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neulasta, Neulasta Onpro (pegfilgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Hematopoietic Subsyndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neupogen (filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation (BMT) Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Autologous Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Hematopoietic Syndrome of Acute Radiation Syndrome Indicated to increase survival in

patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: **Human Immunodeficiency Virus (HIV)-Related Neutropenia** Has been prescribed for HIV-related neutropenia. [11-15, 37]

Hepatitis-C Interferon Induced Neutropenia Neupogen has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Nivestym (filgrastim-aafi, G-CSF), Zarxio (filgrastim-sndz, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Off Label Uses: **Hematopoietic Subsyndrome of Acute Radiation Syndrome** Has been used to increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M]

Hepatitis-C Interferon Induced Neutropenia Has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24, M]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11, 37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs

associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Releuko (filgrastim-ayow)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Off Label Uses: Patients Undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Hematopoietic Subsyndrome of Acute Radiation Syndrome Has been used to increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M]

Hepatitis-C Interferon Induced Neutropenia Has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24, M]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11, 37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Rolvedon (eflapegrastim-xnst)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Rolvedon is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Drug Name: Udenyca (pegfilgrastim-cbqv, G-CSF)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Udenyca is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. **Hematopoietic Subsyndrome of Acute Radiation Syndrome** To increase survival in patients acutely exposed to myelosuppressive doses of radiation. **Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN)** For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]

2 . Criteria

Product Name: Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand

NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	

Approval Criteria

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

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

AND

3 - Patient is 2 years of age or older (applies to Leukine only)

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand

Approval Criteria

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

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

AND

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

- Nivestym
- Zarxio

Product Name: Leukine	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Patient is 55 years of age or older [3, B]

AND

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

Product Name: Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	

RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

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

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand

NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

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

AND

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

- Nivestym
- Zarxio

Product Name: Fulphila, Fylnetra, Granix, Leukine (Off-Label), Neulasta/Neulasta Onpro*, Releuko, Neupogen, Nivestym, Nyvepria, Stimufend, Udenyca/Udenyca Onbody*, Zarxio, or Ziextenzo	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand

GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEULASTA	PEGFILGRASTIM SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157000E520	Brand
NEULASTA ONPRO KIT	PEGFILGRASTIM SOLN PREFILLED SYRINGE KIT 6 MG/0.6ML	8240157000F820	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157010E520	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
STIMUFEND	PEGFILGRASTIM-FPGK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157015E520	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN AUTO-INJECTOR 6 MG/0.6ML	8240157010D520	Brand

ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	Brand
UDENYCA ONBODY	PEGFILGRASTIM-CBQV SOLN PREFILL SYR/INFUSION DEV 6 MG/0.6ML	8240157010E525	Brand

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

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

AND

3 - One of the following:

3.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Notes	*If patient meets criteria above, please approve both Neulasta/Neulasta Onpro, Udenyca/Udenyca Onbody at GPI list “FILGRASTPA”.

Product Name: Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Ziextenzo	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute’s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

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

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen and Granix only):

- Nivestym
- Zarxio

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name: Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ROLVEDON	EFLAPEGRASTIM-XNST SOLN PREFILLED SYRINGE 13.2 MG/0.6ML	8240151880E520	Brand

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

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

AND

3 - Trial and failure or intolerance to ONE of the following:

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name: Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ROLVEDON	EFLAPEGRASTIM-XNST SOLN PREFILLED SYRINGE 13.2 MG/0.6ML	8240151880E520	Brand

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

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

AND

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

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name: Fulphila, Fylnetra, Granix, Leukine, Neulasta/Neulasta Onpro*, Neupogen, Nivestym, Nyvepria, Releuko, Stimufend, Udenyca/Udenyca Onbody*, Zarxio, or Ziextenzo	
Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	3 Months or duration of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEULASTA	PEGFILGRASTIM SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157000E520	Brand
NEULASTA ONPRO KIT	PEGFILGRASTIM SOLN PREFILLED SYRINGE KIT 6 MG/0.6ML	8240157000F820	Brand

NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand
STIMUFEND	PEGFILGRASTIM-FPGK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157015E520	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157010E520	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN AUTO-INJECTOR 6 MG/0.6ML	8240157010D520	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	Brand
UDENYCA ONBODY	PEGFILGRASTIM-CBQV SOLN PREFILL SYR/INFUSION DEV 6 MG/0.6ML	8240157010E525	Brand

Approval Criteria

1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, l]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patient is at high risk for infection-associated complications [16, 17, 34]

AND

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

AND

5 - One of the following:

5.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

5.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Notes	*If patient meets criteria above, please approve both Neulasta/Neulasta Onpro, Udenyca/Udenyca Onbody at GPI list “FILGRASTPA”.

Product Name: Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Ziextenzo	
Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]

Approval Length	3 Months or duration of therapy
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand

Approval Criteria

1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, l]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patient is at high risk for infection-associated complications [16, 17, 34]

AND

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

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen and Granix only):

- Nivestym
- Zarxio

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name: Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand

NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	

Approval Criteria

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3) [16]

AND

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

AND

3 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen

Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand

Approval Criteria

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3) [16]

AND

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

AND

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

- Nivestym
- Zarxio

Product Name: Fulphila (Off-Label), Fylnetra (Off-label), Granix (Off-Label), Leukine, Neulasta, Neupogen, Nivestym (Off-Label), Nyvepria (Off-Label), Releuko (Off-Label), Stimufend (Off-label), Udenyca, Zarxio (Off-Label), or Ziextenzo (Off-Label)	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	1 Months [N]

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEULASTA	PEGFILGRASTIM SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157000E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157010E520	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
STIMUFEND	PEGFILGRASTIM-FPGK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157015E520	Brand
UDENYCA	PEGFILGRASTIM-CBQV SOLN AUTO-INJECTOR 6 MG/0.6ML	8240157010D520	Brand

ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	Brand

Approval Criteria

1 - Patient was/will be acutely exposed to myelosuppressive doses of radiation

AND

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

AND

3 - One of the following:

3.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Granix and Releuko only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Stimufend, Ziextenzo only):

- Neulasta
- Udenyca

Product Name: Fulphila (Off-Label), Fylnetra (Off-Label), Granix (Off-Label), Neupogen, Nyvepria (Off-Label), Ziextenzo	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	1 Months [N]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152070E530	Brand
GRANIX	TBO-FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152070E540	Brand
FULPHILA	PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157020E520	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 300 MCG/ML	82401520702020	Brand
GRANIX	TBO-FILGRASTIM SUBCUTANEOUS INJ 480 MCG/1.6ML (300 MCG/ML)	82401520702030	Brand
NYVEPRIA	PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157002E520	Brand
FYLNETRA	PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157060E520	Brand
ZIEXTENZO	PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML	8240157005E520	Brand

Approval Criteria

1 - Patient was/will be acutely exposed to myelosuppressive doses of radiation

AND

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

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen only):

- Nivestym
- Zarxio

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta
- Udenyca

Product Name: Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Human Immunodeficiency Virus (HIV)-Related Neutropenia (Off-Label)
Approval Length	6 months [11, 15, H]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEUKINE	SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG	82402050002120	Brand
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand

NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	

Approval Criteria

1 - Patient is infected with HIV virus [11- 13]

AND

2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]

AND

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

- Hematologist/oncologist
- Infectious disease specialist

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Human Immunodeficiency Virus (HIV)-Related Neutropenia (Off-Label)
Approval Length	6 months [11, 15, H]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand

Approval Criteria

1 - Patient is infected with HIV virus [11- 13]

AND

2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]

AND

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

- Hematologist/oncologist
- Infectious disease specialist

AND

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

- Nivestym

- Zarxio

Product Name: Neupogen, Nivestym, Releuko, Zarxio	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152060E530	Brand
ZARXIO	FILGRASTIM-SNDZ SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152060E540	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152010E520	Brand
NIVESTYM	FILGRASTIM-AAFI SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152010E530	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 300 MCG/ML	82401520102020	Brand
NIVESTYM	FILGRASTIM-AAFI INJ 480 MCG/1.6ML (300 MCG/ML)	82401520102030	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152015E520	Brand
RELEUKO	FILGRASTIM-AYOW SOLN PREFILLED SYRINGE 480 MCG/0.8ML	8240152015E530	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 300 MCG/ML	82401520152020	Brand
RELEUKO	FILGRASTIM-AYOW INJ SOLN 480 MCG/1.6ML (300 MCG/ML)	82401520152030	Brand

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient is infected with Hepatitis C virus

AND

1.1.2 Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.1.3 Patient has neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells/mm3) after dose reduction of Peg-Intron or Pegasys [F]

OR

1.2 Both of the following:

1.2.1 Patient is experiencing interferon-induced neutropenia (ANC less than or equal to 500 cells/mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 One of the following: [G]

1.2.2.1 Patient with Human Immunodeficiency Virus (HIV) co-infection

OR

1.2.2.2 Status post liver transplant

OR

1.2.2.3 Patient with established cirrhosis

AND

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

- Hematologist/oncologist
- Infectious disease specialist
- Hepatologist
- Gastroenterologist

AND

3 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-Label)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
NEUPOGEN	FILGRASTIM INJ 300 MCG/ML	82401520002010	Brand
NEUPOGEN	FILGRASTIM INJ 480 MCG/1.6ML (300 MCG/ML)	82401520002012	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 300 MCG/0.5ML	8240152000E545	Brand
NEUPOGEN	FILGRASTIM SOLN PREFILLED SYRINGE 480 MCG/0.8ML (600 MCG/ML)	8240152000E550	Brand

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient is infected with Hepatitis C virus

AND

1.1.2 Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.1.3 Patient has neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells/mm3) after dose reduction of Peg-Intron or Pegasys [F]

OR

1.2 Both of the following:

1.2.1 Patient is experiencing interferon-induced neutropenia (ANC less than or equal to 500 cells/mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 One of the following: [G]

1.2.2.1 Patient with Human Immunodeficiency Virus (HIV) co-infection

OR

1.2.2.2 Status post liver transplant

OR

1.2.2.3 Patient with established cirrhosis

AND

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

- Hematologist/oncologist
- Infectious disease specialist
- Hepatologist
- Gastroenterologist

AND

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

- Nivestym
- Zarxio

3 . Background

Benefit/Coverage/Program Information

Table 1. Intergroup C9741 Protocol [19]

Regimen	Drugs	G-CSF
Sequential	Doxorubicin q2 weeks x4 cycles, then paclitaxel q2 weeks x4 cycles, then cyclophosphamide q2 weeks x 4cycles	Days 3 to 10 of each cycle
Concurrent	Doxorubicin + cyclophosphamide q2 weeks x4 cycles, then paclitaxel q2 weeks x4 cycles	Days 3 to 10 of each cycle

Table 2. Examples of chemotherapy regimens with a high risk of FN (> 20%) [16]

Cancer	Regimen
Bladder Cancer	• Dose-dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
Bone Cancer	• VAI (vincristine, doxorubicin or dactinomycin, ifosfamide) • VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide) • Cisplatin/doxorubicin • VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin) • VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)
Breast Cancer[18]	• Dose-dense AC followed by dose-dense paclitaxel (doxorubicin, cyclophosphamide, paclitaxel) • TAX (docetaxel, doxorubicin, cyclophosphamide) • TC (docetaxel, cyclophosphamide) • TCH (docetaxel, carboplatin, trastuzumab)
Colorectal Cancer	• FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, irinotecan)
Head and Neck Squamous Cell Carcinoma	• TPF (docetaxel, cisplatin, 5-fluorouracil)
Hodgkin Lymphoma	• Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine) • Escalated BEACOPP (bleomycin, etoposide, doxorubivin, cyclophosphamide, vincristine, procarbazine, prednisone)
Kidney Cancer	• Doxorubicin/gemcitabine
Non-Hodgkin's Lymphomas	• Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) • ICE (ifosfamide, carboplatin, etoposide) • Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) • MINE (mesna, ifosfamide, mitoxantrone, etoposide) • DHAP (dexamethasone, cisplatin, cytarabine) • ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) • HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone)
Melanoma	• Dacarbazine-based combination with IL-2, interferon alfa (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)

Multiple Myeloma	• DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide) +/- bortezomib (VTD-PACE)
Ovarian Cancer	• Topotecan • Docetaxel
Pancreatic Cancer	• FOLFIRINOX (fluorouracil, leucovorin, irinotecan, oxaliplatin)
Soft Tissue Sarcoma	• MAID (mesna, doxorubicin, ifosfamide, dacarbazine) • Doxorubicin • Ifosfamide/doxorubicin
Small Cell Lung Cancer	• Topotecan
Testicular Cancer	• VIP (etoposide, ifosfamide, cisplatin) • VeIP (vinblastine, ifosfamide, cisplatin) • TIP (paclitaxel, ifosfamide, cisplatin)

Table 3. Examples of chemotherapy regimens with an intermediate risk of FN (10-20%) [16]

Cancer	**Regimen**
Occult Primary-Adenocarcinoma	• Gemcitabine/docetaxel
Breast Cancer	• Docetaxel • AC (doxorubicin, cyclophosphamide) + sequential docetaxel (adjuvant) (taxane portion only) • Paclitaxel every 21 days•
Cervical Cancer	• Cisplatin/topotecan • Paclitaxel/cisplatin • Topotecan • Irinotecan
Colorectal Cancer	• FOLFOX (fluorouracil, leucovorin, oxaliplatin)
Non-Hodgkin's Lymphomas (NHL)[26]	• GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) • CHOP (cyclophosphamide, doxorubivin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin • CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin

	• Bendamustine
Non-Small Cell Lung Cancer	• Cisplatin/paclitaxel • Cisplatin/vinorelbine • Cisplatin/docetaxel • Cisplatin/etoposide • Carboplatin/paclitaxel • Docetaxel
Ovarian Cancer	• Carboplatin/docetaxel
Prostate Cancer	• Cabazitaxel
Testicular Cancer	• Etoposide/cisplatin • BEP (bleomycin, etoposide, cisplatin)
Esophageal and Gastric Cancer	• Irinotecan/cisplatin • Epirubicin/cisplatin/5-flurouracil • Epirubicin/cisplatin/capecitabine
Small Cell Lung Cancer	• Etoposide/carboplatin
Uterine Cancer	• Docetaxel

Table 4. Examples of FDA-approved chemotherapeutic agents with dose-limiting myelosuppression

Generic Name	**Brand Name**
Busulfan	Busulfex®, Myleran®
Carboplatin	Paraplatin®
Carmustine (BCNU)	BiCNU®, Gliadel®
Chlorambucil	Leukeran®
Cladribine	Luestatin®
Cyclophosphamide	Cytoxan®
Cytarabine	N/A
Dacarbazine (DTIC)	DTIC-Dome®
Dactinomycin	Actinomycin D®, Cosmegen®
Daunorubicin	Cerubidine®
Daunorubicin Liposomal	DaunoXome®
Doxorubicin	Adriamycin PFS®, Adriamycin RDF®, Adriamycin®
Doxorubicin Liposomal	Doxil®
Etoposide	Etopophos®, Toposar®, VePesid®
Fluorouracil (5-FU)	Adrucil®, Efudex®, Fluoroplex®
Floxuridine	FUDR®
Fludarabine	Fludara®
Hydroxyurea	Droxia®, Hydrea®
Ifosfamide/Mesna	Ifex®, Mesnex®

Lomustine (CCNU)	CeeNU®
Mechlorethamine (Nitrogen Mustard)	Mustargen®
Melphalan	Alkeran®
Mercaptopurine (6-MP)	Purinethol®
Methotrexate	Rheumatrex®, Trexall®
Mitomycin	N/A
Mitoxantrone	Novantrone®
Paclitaxel	Onxol™, Taxol®
Procarbazine	Matulane®
Teniposide	Vumon®
Thioguanine (6-TG)	Tabloid®
Thiotepa	Thiotepa®
Vinblastine	N/A
Vincristine	Vincasar® PFS
Vinorelbine	Navelbine®

4 . Endnotes

A. Currently there is no information available about the effect of longer acting pegylated G-CSF in patients with myeloid leukemias, therefore pegylated G-CSF should not be used in such patients outside of clinical trials. [17]
B. The safety and efficacy of Leukine in AML induction or consolidation in adults younger than 55 years old have not been established in clinical trials. [3]
C. Per hematology/oncology consultant and member of P&T, most cycles of induction or consolidation chemotherapy last ~ 1 month, but patients who complete therapy typically receive 1 induction and 2-3 consolidations, so re-approval would need to occur every month.
D. The safety and efficacy of pegylated G-CSF has not been fully established in the setting of dose-dense chemotherapy. [17]
E. Per hematology/oncology consultant and member of P&T, in general, dose-dense regimens require growth factor support for chemotherapy administration. [16] Also, Neulasta is commonly used to support dose dense regimens in current community practice. It would be reasonable to allow Neulasta use [in the INT C9741 Protocol] and to broaden its use for other forms of dose dense chemotherapy.
F. The product information for both PEG-Intron and Pegasys recommends dose reduction in patients with neutropenia with an ANC level < 750 cells/mm^3. [21, 22]
G. Per GI consultant and member of P&T, his medical group of practicing hepatologists recommends Neupogen for a special subpopulation of patients with HIV infection, status post liver transplant, or established cirrhosis who experience interferon-induced neutropenia (ANC less than or equal to 500 cells/mm^3) due to treatment with Peg-Intron or Pegasys.
H. Guidelines issued by the U.S. Public Health Service (USPHS) and the Infectious Diseases Society of America (IDSA) recommend for HIV-related neutropenia, the length of therapy with G-CSF and GM-CSF is 2-4 weeks. The clinical benefit of G-CSF therapy

was evaluated in a randomized, double-blind, placebo controlled trial of 30 patients evaluating G-CSF 03 mg/mL subcutaneously 3 times a week or placebo for 12 weeks. The 6 month approval duration mirrors the 6 month approval duration for the erythropoietic agents, as G-CSF has been effective when used alone or in conjunction with epoetin alfa in adults with acquired immunodeficiency syndrome (AIDS) to ameliorate the hematologic toxicity (severe anemia and/or granulocytopenia) associated with zidovudine therapy. [11, 15, 37]

I. Note: This list is NOT inclusive of all chemotherapy regimens with a high risk of FN: See Table 2 in Background section
J. Note: This list is NOT inclusive of all chemotherapy regimens with an intermediate risk of FN: See Table 3 in Background section
K. Risk factors are based on provider information, not the list in the table below. Examples of risk factors may include (but are NOT limited to): Risk factors associated with chemotherapy-induced infection, FN, or neutropenia • Age > 65 years [16, 17] • History of extensive prior chemotherapy or radiation therapy including large radiation ports [16, 17] • Previous episodes of FN [16, 17] • Administration of combined chemoradiotherapy [17] • Pre-existing neutropenia or bone marrow involvement with tumor [16, 17] • Pre-existing conditions [16] • Neutropenia • Active infection/open wounds • Recent surgery • Poor performance status [16, 17] • Poor renal function [16] • Liver dysfunction [16] • Poor nutritional status [17] • More advanced cancer [17] • Hypotension and multiorgan dysfunction (Sepsis syndrome) [16, 17] • Pneumonia [16] • Invasive fungal infection [16, 17] • Other clinically documented infections [16] • Hospitalization at the time of fever [16] • Anticipated prolonged (> 10 days) and profound neutropenia (< 100/mm^3) [17] • Uncontrolled primary disease [17] • Other serious comorbidities [17]
L. Note: This list is NOT all inclusive: See Table 4 in Background section
M. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [33] The American Society of Clinical Oncology states that pegfilgrastim, filgrastim, tbo-filgrastim, and filgrastim-sndz (and other biosimilars as they become available) can be used for the prevention of treatment-related febrile neutropenia. The choice of agent depends on convenience, cost, and clinical situation. [34] NCCN lists FDA-approved biosimilars as appropriate substitutes for filgrastim and pegfilgrastim. Limited data suggest that patients can alternate between the biosimilar and the originator biologic without any clinically meaningful differences regarding efficacy or safety. [16]
N. The efficacy of G-CSFs or GM-CSF for the acute radiation syndrome setting was studied in non-human primate models of radiation injury measuring 60-day survival. An expert panel convened by the World Health Organization recommends that patients receive G-CSF or GM-CSF treatment until their absolute neutrophil count reaches and maintains a level greater than 1.0 x 10^9 cells per liter in the absence of active infection. Patients with severe hematopoietic injury may recover, either spontaneously or after G-CSF treatment alone. In most cases, a duration of two to three weeks would be expected. [1-3, 36]

5 . References

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6 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160833
Guideline Name	Cometriq (cabozantinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cometriq (cabozantinib)
Medullary thyroid cancer Indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC). **Off Label Uses: Non-small cell lung cancer** Has activity against RET gene rearrangements in non-small cell lung cancer (NSCLC). [3]

2 . Criteria

Product Name: Cometriq	
Diagnosis	Medullary Thyroid Cancer (MTC)

Approval Length	11 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COMETRIQ	CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT	21533010106460	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT	21533010106470	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT	21533010106480	Brand

Approval Criteria

1 - Diagnosis of one of the following: [1,2]

- Metastatic medullary thyroid cancer (MTC)
- Unresectable locally advanced MTC

AND

2 - One of the following: [2]

- Patient has symptomatic disease
- Patient has progressive disease

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Cometriq	
Diagnosis	Medullary Thyroid Cancer (MTC)
Approval Length	11 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COMETRIQ	CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT	21533010106460	Brand

COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT	21533010106470	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT	21533010106480	Brand

Approval Criteria

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

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Cometriq	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC) (off-label)
Approval Length	11 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COMETRIQ	CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT	21533010106460	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT	21533010106470	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT	21533010106480	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC) [3]

AND

2 - Presence of RET gene rearrangements as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [3]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Cometriq	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC) (off-label)
Approval Length	11 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COMETRIQ	CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT	21533010106460	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT	21533010106470	Brand
COMETRIQ	CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT	21533010106480	Brand

Approval Criteria

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

Notes	If patient meets criteria above, please approve at GPI-12.

3 . Endnotes

A. In a phase 3 clinical trial of 330 patients, a statistically significant prolongation in progression free survival (PFS) was demonstrated among Cometriq-treated patients compared to those receiving placebo, with a median PFS time of 11.2 months and 4 months in the Cometriq and placebo arms, respectively. [1]

4 . References

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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160834
Guideline Name	Commercial MEDLIMIT CDUR Criteria
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name: Requested opioid pain medication	
Diagnosis	Level of Care Change
Approval Length	1 Time(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
morphine			
opioid			
MED			
cumulative			

MEE			

Approval Criteria

1 - Provider confirms replacement prescription(s) of opioid medication(s) is needed because the patient is physically changing locations and cannot take their prescription with them [such as admission to a long term care (LTC) facility]

Product Name: Requested opioid pain medication	
Diagnosis	Cancer-Related Pain or Sickle Cell Anemia
Approval Length	12 Months to override MME edit
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - Confirmation opioids are being used for the treatment of cancer-related pain or sickle cell anemia

Product Name: Requested opioid pain medication	
Diagnosis	Hospice, Long Term Care, or End-of-Life Care Enrollment
Approval Length	12 Months to override MME edit
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - Patient is currently enrolled in hospice, end-of-life care, or resides in a long term care facility

Product Name: Requested opioid pain medication	
Diagnosis	Other Pain

Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic

Approval Criteria

1 - A written or verbal supporting statement is received from the requesting prescriber attesting that in his/her clinical judgment, the requested dose exceeding the current cumulative morphine milligram equivalent (MME) threshold* is medically required

Notes	*MME is calculated using all of the member's current opioid prescriptions *Note: Ask provider, "Will there be a dose escalation in the patient's opioid utilization in the next 90 days?" If yes, approve MME level 90 daily MME above the rejected level.

2 . Endnotes

A. All opioid medication edits are subject to review and modification (either to increase or decrease existing MME Limits) based on an Exception request received from the member or the member's provider. The decision to remove, modify, or retain an existing restriction on opioid pain medications will be based on evidence of new clinical information which is documented in the form of a written supporting statement received from the prescriber and which contains all of the required elements as outlined in the criteria above.

3 . References

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4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160835
Guideline Name	Compounded Drugs
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name: Compounded drugs**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Compound	compound		
Compounds	compounds		
Bulk powders	bulk powders		
COMPOUNDS	COMPOUNDS		

COMPOUNDED DRUGS	COMPOUNDED DRUGS		
COMPOUND	COMPOUND		
COMPOUNDS	COMPOUNDS		

Approval Criteria

1 - Each active ingredient in the compounded drug is FDA-approved or national compendia* supported for the condition being treated

AND

2 - The therapeutic amounts are supported by national compendia* or two peer-reviewed literature for the condition being treated in the requested route of delivery

AND

3 - If a drug included in the compound requires prior authorization and/or step therapy or is non-formulary, all drug-specific criteria must be met

AND

4 - The compounded drug must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (refer to Table 1)

AND

5 - The patient has tried and failed therapy or had an intolerance to two FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met:

5.1 Patient has a contraindication to commercially available products

OR

5.2 One or no other therapeutic alternatives are commercially available

OR

5.3 Prepared in a strength not commercially available or currently in short supply

OR

5.4 Prepared in a different dosage form for a patient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does NOT meet this criteria).

OR

5.5 Patient has an allergy or sensitivity to inactive ingredients (e.g. dyes, preservatives, sugars, etc.) that are found in commercially available products.

AND

6 - The compounded drug must not be used for a cosmetic purpose.

AND

7 - If the compound is subject to the drug-specific/targeted compound program, the member meets all the applicable drug-specific criteria below for all the targeted ingredient(s) used in the requested compound product.

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. *Approved national compendia are referenced in the "Coverage of Off -Label or Non-FDA Approved Indications" Guideline **Administrative guideline may not apply to all compound reviews, dep ending on the ingredients being used and client elections.

Product Name: Diclofenac compounds**

Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Diclofenac bulk powder			
Diclofenac Ophthalmic Solution			
Arthrotec			
Cambia			
Zorvolex Oral Capsules			
Zipsor Liquid Filled Capsules			
Diclofenac tablets			
Diclofenac tablets			
Dyloject			
Voltaren			
Solaraze			
Pennsaid			
Flector			
Rexaphenac			

Approval Criteria

1 - Compounded drugs that include diclofenac will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Mild to moderate pain
- Pain due to minor strains, sprains or contusions

- Migraine
- Primary dysmenorrhea
- Actinic keratosis
- Ankylosing spondylitis
- Inflammatory disorder of the eye
- Photophobia
- Pain in the eye

AND

1.3 The final dosage form will be for oral, topical, or ophthalmic use

AND

1.4 The final dosage form and strength of the diclofenac ingredient is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the diclofenac targeted compound program.

Product Name: Flurbiprofen compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Flurbiprofen tablets			
Ocufen			

Flurbiprofen bulk powder			

Approval Criteria

1 - Compounded drugs that include flurbiprofen will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Intraoperative miosis inhibition

AND

1.3 The final dosage form will be for oral or ophthalmic use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the flurbiprofen targeted compound program.

Product Name: Fluticasone compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Fluticasone bulk powder			
Cutivate			

Approval Criteria

1 - Compounded drugs that include fluticasone will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 3 months of age or older

AND

1.2 Diagnosis of Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.5 The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)	
Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the fluticasone targeted compound program.

Product Name: Gabapentin compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Gabapentin bulk powder			
Gralise			
Horizant			
Neurontin			

Approval Criteria

1 - Compounded drugs that include gabapentin will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 3 years of age or older

AND

1.2 Patient must have one of the following diagnoses:

- Partial seizures
- Postherpetic neuralgia
- Restless leg syndrome (RLS)

AND

1.3 The final dosage form will be for oral use

AND

1.4 The requested dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available)

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the gabapentin targeted compound program.

Product Name: Ketamine compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Ketamine bulk powder			
Ketalar			

Approval Criteria

1 - Compounded drugs that include ketamine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 16 years of age or older

AND

1.2 One of the following:

1.2.1 Patient is requiring ketamine for conscious sedation prior to a diagnostic or surgical procedure that do not require skeletal muscle relaxation

OR

1.2.2 Patient is requiring ketamine for the induction of anesthesia prior to the administration of other general anesthetic agents

OR

1.2.3 Patient is requiring ketamine as a supplement to low-potency anesthetic agents, such as nitrous oxide

AND

1.3 The final dosage form will be for injection

AND

1.4 The requested dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.6 The requested dose does not exceed the concentration limit of 100mg/mL*

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section.

	*According to the prescribing information, 100mg/ml product must be diluted prior to administration. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the ketamine targeted compound program.

Product Name: Ketoprofen compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Ketoprofen bulk powder			
Ketoprofen extended-release capsules			
Ketoprofen capsules			

Approval Criteria

1 - Compounded drugs that include ketoprofen will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Acute pain
- Primary dysmenorrhea

AND

1.3 The final dosage form will be for oral use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the ketoprofen targeted compound program.

Product Name: Levocetirizine compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Levocetirizine bulk powder			
Xyzal			

Approval Criteria

1 - Compounded drugs that include levocetirizine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 6 months of age or older

AND

1.2 Diagnosis of one of the following:

- Seasonal or perennial allergic rhinitis
- Uncomplicated skin manifestations of chronic idiopathic urticaria

AND

1.3 The final dosage form will be for oral use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the levocetirizine targeted compound program.

Product Name: Mometasone compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Mometasone powder			
Elocon			

Approval Criteria

1 - Compounded drugs that include mometasone will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 2 years of age or older

AND

1.2 Diagnosis of Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.5 The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the mometasone targeted compound program.

Product Name: Acyclovir ointment 5% compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Acyclovir 5% Topical Ointment			
Zovirax 5% Topical Ointment			

Approval Criteria

1 - Compounded drugs that include Acyclovir ointment 5% will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis for one of the following:

- Management of initial genital herpes
- Limited non-life-threatening mucutaneous herpes simplex virus infection in immunocompromised patients

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available)

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may appl y. This drug-specific criteria only applies to clients who enrolled in the Acyclovir ointment 5% targeted compound program.

Product Name: Doxepin cream 5% compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Doxepin 5% Topical Cream			
Prudoxin 5% Topical Cream			
Zonalon 5% Topical Cream			

Approval Criteria

1 - Compounded drugs that include Doxepin cream 5% will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Treatment of moderate pruritus with atopic dermatitis or lichen simplex chronicus

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available)

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the Doxepin cream 5% targeted compound program.

2 . Background

Benefit/Coverage/Program Information

Table 1: Drugs that were withdrawn from the market due to safety or effectiveness

3,3',4',5-tetrachlorosalicylanilide	Methopholine Methoxylflurane
Adenosine phosphate	Methoxyflurane
Adrenal cortex	Mibefradil dihydrochloride
Alatrofloxacin mesylate	Nitrofurazone
Aminopyrine	Nomifensine maleate
Astemizole	Novobiocin
Azaribine	Ondansetron hydrochloride
Benoxaprofen	Oxyphenisatin
Bithionol	Oxyphenisatin acetate
Bromfenac sodium	Pemoline
Bromocriptine mesylate	Pergolide mesylate
Butamben	Phenacetin
Camphorated oil	Phenformin hydrochloride
Carbetapentane citrate	Phenylpropanolamine
Casein, iodinated	Pipamazine
Cerivastatin sodium	Polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride, and bisacodyl
Chloramphenicol	

Chlorhexidine gluconate	Potassium arsenite
Chlormadinone acetate	Potassium chloride
Chloroform	Povidone
Cisapride	Propoxyphene
Cobalt	Rapacuronium bromide
Dexfenfluramine hydrochloride	Reserpine
Diamthazole dihydrochloride	Rofecoxib
Dibromsalan	Sibutramine hydrochloride
Diethylstilbestrol	Sparteine sulfate
Dihydrostreptomycin sulfate	Sulfadimethoxine
Dipyrone	Sulfathiazole
Encainide hydrochloride	Suprofen
Esmolol hydrochloride	Sweet spirits of nitre
Etretinate	Tegaserod maleate
Fenfluramine hydrochloride	Temafloxacin hydrochloride
Flosequinan	Terfenadine
Gatifloxacin	Tetracycline
Gelatin	Ticrynafen
Glycerol, iodinated	Tribromsalan
Gonadotropin, chorionic	Trichloroethane
Grepafloxacin	Troglitazone
Mepazine	Trovafloxacin mesylate

Metabromsalan	Urethane
Methamphetamine hydrochloride	Valdexocib
Methapyrilene	Vinyl chloride
	Zirconium
	Zomepirac sodium

Diclofenac Compounds

There is little to no evidence-based literature support for the use of diclofenac for indications and in dosage forms not currently approved by the FDA. Use of compounds containing diclofenac should be limited to the following FDA-approved indications.

1. Diclofenac is indicated for a number of conditions including:
• Management of mild to moderate acute pain or osteoarthritis pain,
• Relief of signs and symptoms of ankylosing spondylitis and rheumatoid arthritis
• Relieve acute pain associated with minor sprains, strains, and contusions
• Treatment of primary dysmenorrhea
• Treatment of acute migraine attacks with or without aura in adults
• Treatment of actinic keratosis
• Treatment of postoperative inflammation in patients who have undergone cataract surgery and temporary relief of pain and photophobia associated with corneal refractive surgery.

2. Safety and efficacy in pediatric populations has not been established.

3. Diclofenac is commercially available in the several dosage forms: oral capsules, oral tablets, oral solution, topical patch, topical gel, topical solution, topical ointment and ophthalmic solution.

Flurbiprofen Compounds

There is little to no evidence-based literature support for the use of flurbiprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing flurbiprofen should be limited to the following FDA-approved indications.

- Flurbiprofen tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Flurbiprofen ophthalmic solution is indication for preventing intraoperative miosis.

- Flurbiprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Flurbiprofen is commercially available as a 50 and 100 mg oral tablet and also as 0.03% sterile ophthalmic solution.

Fluticasone Compounds

There is little to no evidence-based literature support for the use of fluticasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing fluticasone should be limited to the following FDA-approved indications.

- Fluticasone cream indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 3 months of age or older.

Fluticasone is commercially available in the several dosage forms: topical cream, topical lotion, topical ointment, nasal spray and various aerosols and powders for inhalation

Gabapentin Compounds

There is little to no evidence-based literature support for the use of gabapentin for indications or in dosage forms not currently approved by the FDA. Use of compounds containing gabapentin should be limited to the following FDA-approved indications.

- Gabapentin is indicated for treatment postherpetic neuralgia in adults (Gralise prescribing information, 2023; Horizant prescribing information, 2020; Neurontin prescribing information, 2020).
- Gabapentin is indicated as adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy (Neurontin prescribing information, 2020).
- Gabapentin is indicated for the treatment of moderate to severe primary restless leg syndrome (Horizant prescribing information, 2020).

Ketamine Compounds

There is little to no evidence-based literature support for the use of ketamine for indications or in dosage forms not currently approved by the FDA. Use of compounds containing ketamine should be limited to the following FDA-approved indications.

- Ketamine is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation (Ketalar prescribing information, 2022)

- Ketamine is indicated for the induction of anesthesia prior to the administration of other general anesthetic agents (Ketalar prescribing information, 2022)
- Ketamine is indicated to supplement low-potency agents, such as nitrous oxide (Ketalar prescribing information, 2022)
- Esketamine (the S-enantiomer of racemic ketamine) is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults (Spravato prescribing information, 2023). Coverage of compounds with racemic ketamine will continue to be limited to the FDA approved indications listed above.

Ketoprofen Compounds

There is little to no evidence-based literature support for the use of ketoprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing ketoprofen should be limited to the following FDA-approved indications.

- Ketoprofen immediate-release capsules and ketoprofen extended-release capsules are indicated for the management of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Ketoprofen immediate-release capsules are indicated for the management of pain and for treatment of primary dysmenorrhea.
- Ketoprofen extended-release capsules are not recommended for treatment of acute pain because of its extended-release characteristics.
- Ketoprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Ketoprofen is commercially available as a 50 and 75 mg oral capsule and 200 mg extended release oral capsule.

Levocetirizine Compounds

There is little to no evidence-based literature support for the use of levocetirizine for indications and in dosage forms not currently approved by the FDA. Use of compounds containing levocetirizine should be limited to the following FDA-approved indications.

- Levocetirizine dihydrochloride, a histamine (H1) receptor antagonist, is indicated for:
    - Treatment of perennial allergic rhinitis in adults and children 6 months of age or older.
    - Treatment of seasonal allergic rhinitis in adults and children 2 years of age and older
    - Uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older

- Levocetirizine is commercially available as a 5 mg oral tablet and 2.5 mg/mL oral solution.

Mometasone Compounds

There is little to no evidence-based literature support for the use of mometasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing mometasone should be limited to the following FDA-approved indications.

- Mometasone cream & ointment are indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥ 2 years of age.
- Mometasone lotion is indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥12 years of age.
- Mometasone is commercially available in several dosage forms: topical cream, topical lotion, topical ointment, nasal spray, powder for inhalation and sinus implant.

Acyclovir ointment 5% Compounds

There is little to no evidence-based literature support for the use of Acyclovir ointment 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Acyclovir ointment 5% should be limited to the following FDA-approved indications.

- Acyclovir ointment 5% is indicated for the management of initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infection in immunocompromised patients.
- Acyclovir is commercially available in several dosage forms: topical ointment, topical cream, buccal tablet, tablet, capsule, oral suspension, and intravenous solution.

Doxepin cream 5% Compounds

There is little to no evidence-based literature support for the use of Doxepin cream 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Doxepin cream 5% should be limited to the following FDA-approved indications.

- Doxepin cream 5% is indicated for short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.
- Doxepin cream 5% is commercially available in several dosage forms: topical cream, capsule, tablet, and oral concentrate

3 . Endnotes

A. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. [1]
B. Compound drugs are customized in the following ways to meet patients need: (1) Removal of a nonessential ingredient for patients' allergies; and (2) Change in medication formulation (e.g., pill to solution in a patient with swallowing difficulties). [1]
C. Benefit design recommendations provided in the OptumRx Commercial Implementation Guide: (1) $200 Rx High Dollar Limit at Retail; (2) The processing of compound drugs will be subject to the same benefit plan edits: day supply, copay and drug coverage; (3) Multiple ingredient processing is recommended; (4) Bulk chemicals and compound kit recommended as standard exclusions.
D. Compounding does not generally include mixing or reconstituting commercially available products in accordance with the manufacturer’s instructions or the product’s approved labeling.

4 . References

1. Compounding and the FDA: Questions and Answers. Available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm. Accessed July 1, 2024.
2. Application of Federal Low to Practice of Pharmacy Compounding. Available at: https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm155666.htm. Accessed July 1, 2024.
3. Drugs withdrawn or removed from the market for reasons of safety and effectiveness. Available at: https://www.ecfr.gov/cgi-bin/text-idx?SID=427cfbadfcc9a0a3cee36b57e99712ad&mc=true&node=se21.4.216_124&rgn=div8.Accessed July 1, 2024.
4. DRUGDEX [Internet database]. Greenwood Village, CO: Thomson MICROMEDEX, updated periodically. Accessed July 1, 2024.
5. Flurbiprofen Tablet Prescribing Information. Teva Pharmaceuticals. Parsippany, NJ. November 2021.
6. Gralise prescribing information. Almatica Pharma LLC. Morristown, NJ. April 2023.
7. Horizant prescribing information. Arbor Pharmaceuticals, LLC. Atlanta, GA. April 2020.
8. Neurontin prescribing information. Pfizer. New York, NY. December 2020.
9. Ketalar prescribing information. Par Pharmaceutical. Chestnut Ridge, NY. June 2022.
10. Ketoprofen Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. March 2021.
11. Spravato Prescribing Information. Janssen Pharmaceuticals. Titusville, NJ. October 2023.
12. Sinuva Prescribing Information. Intersect ENT, Inc. Menlo Park, CA. January 2023.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-158669
Guideline Name	Constipation Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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	
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

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: Motegrity, Trulance	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TRULANCE	PLECANATIDE TAB 3 MG	52543060000320	Brand
MOTEGRITY	PRUCALOPRIDE SUCCINATE TAB 1 MG (BASE EQUIVALENT)	52560060200320	Brand
MOTEGRITY	PRUCALOPRIDE SUCCINATE TAB 2 MG (BASE EQUIVALENT)	52560060200330	Brand

Approval Criteria

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

AND

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

- Lactulose
- Polyethylene glycol

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to Linzess

AND

4 - For Trulance, trial and failure (of a minimum 30 days supply), contraindication, or intolerance to generic lubiprostone

Product Name: Relistor injection, Relistor tablet	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
RELISTOR	METHYLNALTREXONE BROMIDE INJ 12 MG/0.6ML (20 MG/ML)	52580050102020	Brand
RELISTOR	METHYLNALTREXONE BROMIDE INJ 8 MG/0.4ML (20 MG/ML)	52580050102015	Brand
RELISTOR	METHYLNALTREXONE BROMIDE TAB 150 MG	52580050100320	Brand

Approval Criteria

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

AND

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

- Lactulose
- Polyethylene glycol

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following preferred brands: [B]

- Movantik
- Symproic

AND

4 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to generic lubiprostone

3 . Endnotes

A. Stimulant and osmotic laxatives should be tried/failed first before patients are placed on OIC agents (ie, Relistor and Movantik). [2, 3]
B. The 2019 American Gastroenterological Association (AGA) Guideline for Opioid-Induced Constipation (OIC) recommends traditional laxative therapy as first-line agents given their established efficacy, safety, and lower cost. If an adequate trial of laxatives does not optimally control symptoms, the AGA recommends treatment with peripherally acting mu-opioid receptor antagonist (PAMORA) drugs with higher quality evidence of efficacy, namely naldemedine and naloxegol. [2]

4 . References

1. Relistor Prescribing Information. Salix Pharmaceuticals. Bridgewater, NJ. April 2020.
2. Per clinical consult with gastroenterologist, February 19, 2019.
3. Crockett SD, Greer KB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. Gastroenterology. Gastroenterology. 2019;156:218-226.
4. Movantik Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. April 2020.
5. Symproic Prescribing Information. BioDelivery Sciences International Inc. Raleigh, NC. July 2021.
6. Linzess Prescribing Information. Allergan USA, Inc. Madison, NJ. June 2023.
7. Trulance Prescribing Information. Salix Pharmaceuticals Inc. Bridgewater, NJ. April 2021.
8. Amitiza Prescribing Information. Takeda Pharmaceuticals America, Inc. Deerfield, IL. November 2020.
9. Motegrity Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. November 2020.
10. Ford AC, Moayyedi P, Chey WD, Harris LA, Lacy BE, Saito YA, Quigley EMM; ACG Task Force on Management of Irritable Bowel Syndrome. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. Am J Gastroenterol. 2018 Jun;113(Suppl 2):1-18.

Prior Authorization Guideline

Guideline ID	GL-158670
Guideline Name	Continuous Glucose Monitors, Sensors, and Transmitters - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name: Dexcom Products*, Freestyle Libre Products*			
Approval Length	12 month(s)		
Therapy Stage	Initial Authorization		
Guideline Type	Prior Authorization		
Product Name	**Generic Name**	**GPI**	**Brand/Generic**
DEXCOM G6 RECEIVER	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 14 DAY/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 2/READER/FLASH	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand

GLUCOSE MONITORING SYSTEM			
FREESTYLE LIBRE/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
DEXCOM G6 SENSOR	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 14 DAY/SENSOR/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 2/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
DEXCOM G6 TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
DEXCOM G7 SENSOR	CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
DEXCOM G7 RECEIVER	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 3/READER/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 3/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 3 PLUS/SESOR/GLUCOSE MONITORING SYSTEM	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of diabetes mellitus

AND

1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support

AND

1.3 ONE of the following:

1.3.1 Patient is being treated with insulin

OR

1.3.2 Patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan
- Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

Notes	*If patient meets criteria above, please approve all CGM components at NDC list “PREFCGMPA”

Product Name: Dexcom Products*, Freestyle Libre Products*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEXCOM G6 RECEIVER	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 14 DAY/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 2/READER/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
DEXCOM G6 SENSOR	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand

FREESTYLE LIBRE 14 DAY/SENSOR/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 2/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
DEXCOM G6 TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
DEXCOM G7 SENSOR	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
DEXCOM G7 RECEIVER	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 3/READER/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 3/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 3 PLUS/SESOR/GLUCOSE MONITORING SYSTEM	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand

Approval Criteria

1 - ONE of the following:

1.1 Patient demonstrates positive clinical response as evidenced by ONE of the following:

- Improvement in glycemic control (e.g., lower and/or maintain A1C levels)
- Reduction or improvement in hypoglycemic events

OR

1.2 Patient is being assessed by the prescriber for adherence to their CGM regimen and diabetes treatment plan

Notes	*If patient meets criteria above, please approve all CGM components at NDC list “PREFCGMPA”

Product Name: All Other Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GUARDIAN REAL-TIME REPLACEMENT MONITOR PEDIATRIC	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
ENLITE GLUCOSE SENSOR	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE SENSOR/HOLDER	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN SENSOR (3)	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN SENSOR 3	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE SMART TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN CONNECT TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN CONNECT TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN LINK 3 TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINILINK REAL-TIME TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINIMED GUARDIAN LINK 3 TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINIMED 630G GUARDIAN PRESS STARTER TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
PARADIGM REAL-TIME TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
BIGFOOT UNITY PROGRAM KIT	*BLOOD GLUCOSE MONITOR KIT W/ MONITOR DEVICE & DIGITAL APP**	97202010006419	Brand
EVERSENSE E3 SENSOR/HOLDER	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand

EVERSENSE E3 SMART TRANSMITTER	*CONTINUOUS GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN 4 GLUCOSE SENSOR	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN 4 TRANSMITTER KIT	*CONTINUOUS GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of diabetes mellitus

AND

1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support

AND

1.3 ONE of the following:

1.3.1 Patient is being treated with insulin

OR

1.3.2 Patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan
- Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

AND

1.4 Both of the following:

1.4.1 Minimum 90 day trial within the last 180 days, to both of the following:

- Dexcom Products
- Freestyle Products

AND

1.4.2 Valid clinical rationale provided, explaining how the requested device is the only product that will provide benefit when the Dexcom and Freestyle products have not shown to be effective

Notes	*If patient meets criteria above, please approve all CGM components at GPI list “CGMPA”

Product Name: All Other Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GUARDIAN REAL-TIME REPLACEMENT MONITOR PEDIATRIC	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
ENLITE GLUCOSE SENSOR	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE SENSOR/HOLDER	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN SENSOR (3)	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN SENSOR 3	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE SMART TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN CONNECT TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN CONNECT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand

TRANSMITTER KIT			
GUARDIAN LINK 3 TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINILINK REAL-TIME TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINIMED GUARDIAN LINK 3 TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
MINIMED 630G GUARDIAN PRESS STARTER TRANSMITTER KIT	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
PARADIGM REAL-TIME TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
BIGFOOT UNITY PROGRAM KIT	*BLOOD GLUCOSE MONITOR KIT W/ MONITOR DEVICE & DIGITAL APP**	97202010006419	Brand
EVERSENSE E3 SENSOR/HOLDER	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE E3 SMART TRANSMITTER	*CONTINUOUS GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
GUARDIAN 4 GLUCOSE SENSOR	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
GUARDIAN 4 TRANSMITTER KIT	*CONTINUOUS GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand

Approval Criteria

1 - ONE of the following:

1.1 Patient demonstrates positive clinical response as evidenced by ONE of the following:

- Improvement in glycemic control (e.g., lower and/or maintain A1C levels)
- Reduction or improvement in hypoglycemic events

OR

1.2 Patient is being assessed by the prescriber for adherence to their CGM regimen and diabetes treatment plan

AND

2 - Minimum 90 day trial to both of the following:

- Dexcom Products
- Freestyle Products

Notes	*If patient meets criteria above, please approve all CGM components at GPI list “CGMPA”

Product Name: Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EVERSENSE SENSOR/HOLDER	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE SMART TRANSMITTER	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
BIGFOOT UNITY PROGRAM KIT	*BLOOD GLUCOSE MONITOR KIT W/ MONITOR DEVICE & DIGITAL APP**	97202010006419	Brand
FREESTYLE LIBRE 14 DAY/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 2/READER/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE/READER/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand
FREESTYLE LIBRE 14 DAY/SENSOR/FLASH MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 2/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
FREESTYLE LIBRE 3/READER/FLASH	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***	97202012026200	Brand

GLUCOSE MONITORING SYSTEM			
FREESTYLE LIBRE 3/SENSOR/FLASH GLUCOSE MONITORING SYSTEM	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE E3 SENSOR/HOLDER	*CONTINUOUS GLUCOSE SYSTEM SENSOR***	97202012046300	Brand
EVERSENSE E3 SMART TRANSMITTER	*CONTINUOUS GLUCOSE SYSTEM TRANSMITTER***	97202012066300	Brand
FREESTYLE LIBRE 3 PLUS/SENSOR/GLUCOSE MONITORING SYSTEM	CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***	97202012046300	Brand

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of diabetes mellitus

AND

1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support

AND

1.3 ONE of the following:

1.3.1 Submission of medical records (e.g., chart notes) or paid claims confirming patient is being treated with insulin

OR

1.3.2 Submission of medical records (e.g., chart notes) confirming patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan

• Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia **AND** **1.4** Both of the following (Applies to all products except Dexcom): **1.4.1** Submission of medical records (e.g., chart notes) or paid claims confirming minimum 90 day trial within the last 180 days, to Dexcom products **AND** **1.4.2** Submission of medical records (e.g., chart notes) providing valid clinical rationale explaining how the requested device is the only product that will provide benefit when Dexcom products have not shown to be effective	
Notes	*If patient meets criteria above, please approve all CGM components at GPI list “CGMPA”

2 . Endnotes

A. People who have been using continuous glucose monitoring, continuous subcutaneous insulin infusion, and/or automated insulin delivery for diabetes management should have continued access across third party payers. Interruption of access to CGM is associated with a worsening of outcomes, therefore, it is important for individuals on CGM to have consistent access. [2]

3 . References

1. CMS. Provider compliance tips for glucose monitors & diabetic accessories/supplies. CMS Website. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822. Accessed March 21, 2023.
2. American Diabetes Association. Diabetes Care. Available at Volume 45 Issue Supplement_1 Diabetes Care | American Diabetes Association (diabetesjournals.org). Available at https://diabetesjournals.org/care/issue/45/Supplement_1. Accessed April 12, 2022.
3. BigFoot Unity PDF. Available at: https://f.hubspotusercontent40.net/hubfs/5085144/PDFs/Bigfoot%20Unity%E2%84%A2%20System%20User%20Guide.pdf. Accessed May 23, 2023.

Prior Authorization Guideline

Guideline ID	GL-160836
Guideline Name	Copper Chelating Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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., Humira (adalimumab), Enbrel (etanercept)), Non-TNF biologic (e.g., Rinvoq (upadacitinb), Xeljanz (tofacitinib)]

AND

3 - Trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Wilson's disease, Cystinuria, Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Wilson's Disease
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg
- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

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

- Gastroenterologist
- Hepatologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Cystinuria
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Diagnosis of cystinuria

AND

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

- Urinary alkalinization therapy [4]
- Thiola (tiopronin) [A]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

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

- Nephrologist
- Urologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CUPRIMINE	PENICILLAMINE CAP 250 MG	99200030000110	Brand
PENICILLAMINE	PENICILLAMINE CAP 250 MG	99200030000110	Generic

Approval Criteria

1 - Diagnosis of severe, active rheumatoid arthritis

AND

2 - Patient's condition is unresponsive to conventional therapy [e.g., traditional DMARDs (e.g., methotrexate, sulfasalazine), TNF inhibitor (e.g., Humira (adalimumab), Enbrel (etanercept)), Non-TNF biologic (e.g., Rinvoq (upadacitinb), Xeljanz (tofacitinib)]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Brand Syprine, generic trientine, Cuvrior	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYPRINE	TRIENTINE HCL CAP 250 MG	99200020100110	Brand
TRIENTINE HYDROCHLORIDE	TRIENTINE HCL CAP 250 MG	99200020100110	Generic
CUVRIOR	TRIENTINE TETRAHYDROCHLORIDE TAB 300 MG	99200020200330	Brand
TRIENTINE HYDROCHLORIDE	TRIENTINE HCL CAP 500 MG	99200020100130	Generic

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Documentation of one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg
- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Trial and failure, contraindication, or intolerance to Depen (penicillamine) tablets

AND

4 - For Brand Syprine and Cuvrior, trial and failure, or intolerance to generic trientine

AND

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

- Gastroenterologist
- Hepatologist

Product Name: Brand Syprine, generic trientine, Cuvrior	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYPRINE	TRIENTINE HCL CAP 250 MG	99200020100110	Brand

TRIENTINE HYDROCHLORIDE	TRIENTINE HCL CAP 250 MG	99200020100110	Generic
CUVRIOR	TRIENTINE TETRAHYDROCHLORIDE TAB 300 MG	99200020200330	Brand
TRIENTINE HYDROCHLORIDE	TRIENTINE HCL CAP 500 MG	99200020100130	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - For Brand Syprine and Cuvrior, trial and failure, or intolerance to generic trientine

Product Name: Cuvrior, Brand Syprine	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CUVRIOR	TRIENTINE TETRAHYDROCHLORIDE TAB 300 MG	99200020200330	Brand
SYPRINE	TRIENTINE HCL CAP 250 MG	99200020100110	Brand

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg

- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Depen (penicillamine) tablets

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic trientine

AND

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

- Gastroenterologist
- Hepatologist

3 . Endnotes

A. Cystine-binding thiol drugs should be offered to patients with cysteine stones who are unresponsive to dietary modification and urinary alkalinization [3]. Tiopronin should be considered first as it is possibly more effective and associated with fewer adverse events than d-penicillamine.

4 . References

1. Cuprimine prescribing information. Bausch Health US, LLC. Bridgewater, NJ. October 2020.
2. Syprine prescribing information. Bausch Health US, LLC. Bridgewater, NJ. September 2020.
3. Pearle MS, Goldfarb DS, Assimos DG, et al. Medical management of kidney stones: AUA guideline. J Urol. 2014 Aug;192(2):316-24.
4. Fattah H, Hambaroush Y, Goldfarb DS. Cystine nephrolithiasis. Transl Androl Urol. 2014 Sep 1;3(3):228-233. doi: 10.3978/j.issn.2223-4683.2014.07.04.

5. European Association for Study of Liver. EASL Clinical Practice Guidelines: Wilson's disease. J Hepatol. 2012;56(3):671-685.
6. Cuvrior Prescribing Information. Orphalan SA. Chicago, IL. May 2022.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160837
Guideline Name	Corlanor (ivabradine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Corlanor (ivabradine)
Chronic Heart Failure Indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic, chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use. **Heart Failure due to Dilated Cardiomyopathy (DCM)** Indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate. **Off Label Uses: Inappropriate Sinus Tachycardia (IST)** Has been used for the treatment of inappropriate sinus tachycardia (IST). [7]

2 . Criteria

Product Name: Brand Corlanor, generic ivabradine	
Diagnosis	Chronic Heart Failure
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CORLANOR	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Brand
CORLANOR	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Brand
CORLANOR	IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV)	40700035102020	Brand
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Generic
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Generic

Approval Criteria

1 - Diagnosis of chronic heart failure [3, 5]

AND

2 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms [3, 5, A]

AND

3 - Patient has a left ventricular ejection fraction of less than or equal to 35% [3, 5]

AND

4 - Patient is in sinus rhythm [3, 5]

AND

5 - Patient has a resting heart rate that is greater than or equal to 70 beats per minute [3, 5, E]

AND

6 - Trial and failure, contraindication, or intolerance to all of the following at a maximally tolerated dose: [10]

6.1 One of the following:

- Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)
- Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)]

AND

6.2 One of the following: [3, 5, 10, B-F]

- bisoprolol
- carvedilol
- metoprolol succinate extended-release

AND

6.3 Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformn)]

AND

6.4 Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]

AND

7 - Patient has been hospitalized for worsening heart failure in the previous 12 months [3]

AND

8 - Prescribed by or in consultation with a cardiologist

Product Name: Brand Corlanor, generic ivabradine	
Diagnosis	Heart Failure due to Dilated Cardiomyopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CORLANOR	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Brand
CORLANOR	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Brand
CORLANOR	IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV)	40700035102020	Brand
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Generic
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Generic

Approval Criteria

1 - Diagnosis of heart failure due to dilated cardiomyopathy

AND

2 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms [6]

AND

3 - Patient is in sinus rhythm

AND

4 - Patient has an elevated heart rate

AND

5 - Trial and failure, contraindication, or intolerance to one of the following: [1, 4, 6]

- Beta blocker (e.g., bisoprolol, metoprolol succinate extended release)
- Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Diuretic Agent (e.g., spironolactone, furosemide)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Brand Corlanor, generic ivabradine	
Diagnosis	Inappropriate Sinus Tachycardia (IST) [off-label]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CORLANOR	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Brand
CORLANOR	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Brand
CORLANOR	IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV)	40700035102020	Brand
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Generic
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Generic

Approval Criteria

1 - Diagnosis of inappropriate sinus tachycardia (IST) confirmed by both of the following: [7]

- Sinus heart rate greater than 100 beats per minute at rest
- A mean 24 hour heart rate greater than 90 beats per minute

AND

2 - Other causes of sinus tachycardia have been ruled out (e.g., hyperthyroidism, anemia, illicit stimulant drug use, caffeine, etc.) [7]

AND

3 - Provider attests that symptoms of IST are causing significant functional impairment or distress (e.g., palpitations, light-headedness, syncope, chest pain, dyspnea, etc.) [8, 9]

AND

4 - Prescribed by or in consultation with a cardiologist

Product Name: Brand Corlanor, generic ivabradine	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CORLANOR	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Brand
CORLANOR	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Brand
CORLANOR	IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV)	40700035102020	Brand
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 5 MG (BASE EQUIV)	40700035100320	Generic
IVABRADINE HYDROCHLORIDE	IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)	40700035100330	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, patients' heart failure was defined as New York Heart Association class II, III or IV [1, 3]
B. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, the main reasons for not achieving guideline-recommended doses of beta-blocker therapy were hypotension, fatigue, dyspnea, dizziness, history of cardiac decompensation, and bradycardia [1, 3]
C. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, the main reasons that patients were unable to receive beta-blocker therapy were due to a diagnosis of chronic obstructive pulmonary disease, hypotension or asthma [1, 3]
D. The following are examples of contraindications to beta-blocker therapy but is not a comprehensive list: severe bradycardia, decompensated cardiac failure, cardiogenic shock, second-or-third degree heart block, sick sinus syndrome (without a functional permanent pacemaker) [4]
E. Corlanor slows the heart rate by inhibiting the cardiac pacemaker If current and therefore heart rate should be at or above 70 beats per minute prior to initiation of therapy to ensure bradycardia does not ensue following initiation of therapy with Corlanor [2]
F. Per 2022 AHA/ACC/HFSA guideline for the management of Heart Failure, three beta blockers have been shown to be effective in reducing the risk of death in patients with HFrEF: bisoprolol, metoprolol succinate, and carvedilol. [10]

4 . References

1. Corlanor Prescribing Information. Amgen Inc. Thousand Oaks, CA. April 2019.
2. Ivabradine (Corlanor) for heart failure. Med Lett Drugs Ther. 2015 May 25; 57 (1469): 75-6.
3. Swedberg K, Komajda M, Bohm M, et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomized placebo-controlled study. Lancet. 2010 Sep 11;376(9744):875-85.
4. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc; Updated periodically. Available by subscription at: http://www.thomsonhc.com/. Accessed June 25, 2020.
5. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical

Practice Guidelines and the Heart Failure Society of America. J Am Coll Cardiol. 2017 Aug 8;70(6):776-803.
6. Bonnet D, Berger F, Jokinen E, et al. Ivabradine in children with dilated cardiomyopathy and symptomatic chronic heart failure. J Am Coll Cardiol. 2017 Sep 5;70(10):1262-1272.
7. Page RL, Joglar JA, Caldwell MA, et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2016 Apr 5;67(13):e27-e115.
8. Cappato R, Castelvecchio S, Ricci C, et al. Clinical efficacy of ivabradine in patients with inappropriate sinus tachycardia: a prospective, randomized, placebo-controlled, double-blind, crossover evaluation. J Am Coll Cardiol. 2012 Oct 9;60(15):1323-9.
9. Sheldon RS, Grubb BP 2nd, Olshansky B, et al. 2015 heart rhythm society expert consensus statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope. Heart Rhythm. 2015 Jun;12(6):e41-63.
10. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. Journal of Cardiac Failure. Published online April 2022.

5 . Revision History

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

Prior Authorization Guideline

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

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name: Cosentyx SC	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand

COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

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

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with a dermatologist

AND

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

- corticosteroids (e.g., betamethasone, clobetasol)

- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name: Cosentyx SC	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

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

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

Product Name: Cosentyx IV & SC

Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

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

AND

3 - One of the following:

- Cosentyx SC: Patient is 2 years of age or older
- Cosentyx IV: Patient is 18 years of age or older

AND

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

- Dermatologist
- Rheumatologist

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name: Cosentyx IV & SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

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

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

Product Name: Cosentyx IV & SC	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

Notes	** For review process only: Refer to the table in the Background section for carrier-specific formulary products

Product Name: Cosentyx IV & SC	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

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

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)

- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Cosentyx IV & SC	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

Product Name: Cosentyx IV & SC	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand
COSENTYX	SECUKINUMAB IV SOLN 125 MG/5ML	90250575002050	Brand

Approval Criteria

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

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

Product Name: Cosentyx SC	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

1 - Diagnosis of active enthesitis-related arthritis

AND

2 - Patient is 4 years of age or older

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

Product Name: Cosentyx SC	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

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

- Reduction in the total active (swollen and tender) joint count from baseline

- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Cosentyx SC	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

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

AND

2 - Prescribed by or in consultation with a dermatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one oral antibiotic (e.g., clindamycin, rifampin, tetracycline) [7]

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary products

Product Name: Cosentyx SC	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	9025057500D520	Brand
COSENTYX SENSOREADY PEN	SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150 MG/ML (300 MG DOSE)	9025057500D530	Brand
COSENTYX UNOREADY	SECUKINUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	9025057500D550	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	9025057500E510	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	9025057500E520	Brand
COSENTYX	SECUKINUMAB SUBCUTANEOUS PREF SYR 150 MG/ML (300 MG DOSE)	9025057500E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 7]:

- Reduction in the abscess and inflammatory nodule count from baseline
- Reduced formation of new sinus tracts and scarring
- Improvement in symptoms (e.g., pain, suppuration) from baseline

2 . References

1. Cosentyx prescribing information. Novartis Pharmaceuticals Corp. East Hanover, NJ. October 2023.

2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
6. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Care Res. 2019;71(6):717-734.
7. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: a publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019;81(1):91-101.

3 . Revision History

Date	Notes
12/20/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-160449
Guideline Name	Cosentyx (secukinumab) - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cosentyx SC (secukinumab)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy. **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. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)** Indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. **Enthesitis-Related Arthritis (ERA)** Indicated for the treatment of active enthesitis-related arthritis in patients 4 years of age and older.

Hidradenitis Suppurativa (HS) Indicated for the treatment of adult patients with moderate to severe hidradenitis suppurativa (HS).
Drug Name: Cosentyx IV (secukinumab)
Psoriatic Arthritis (PsA) 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. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)** Indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

2 . 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 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

6 - Both of the following:

6.1 One of the following:

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

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Skyrizi (risankizumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

OR

6.1.2 Both of the following:

6.1.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

6.1.2.2 Documentation of positive clinical response to therapy as evidenced by ONE of the following [2]:

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

AND

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary adalimumab 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 the BSA involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

Product Name: Cosentyx SC	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum

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

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

6 - Both of the following:

6.1 One of the following:

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

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Skyrizi (risankizumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

OR

6.1.2 Both of the following:

6.1.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

6.1.2.2 Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

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

AND

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

Notes	* For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products

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

AND

5 - One of the following:

5.1 Both of the following:

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

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Rinvoq/LQ (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

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

- Orencia (abatacept)
- Taltz (ixekizumab)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by 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	* For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab 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	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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

AND

5 - One of the following:

5.1 Both of the following:

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

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Rinvoq/LQ (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

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

- Orencia (abatacept)
- Taltz (ixekizumab)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by 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

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary adalimumab products

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 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

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 Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

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

Notes	*Includes attestation that a total of two TNF inhibitors have already 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: 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	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

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 Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

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

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. ** For review process only: Refer to the table in the Background section for carrier-specific formulary adalimumab products

Product Name: 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 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

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

- Cimzia (certolizumab pegol)
- Taltz (ixekizumab)
- Rinvoq (upadacitinib)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

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

Product Name: 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 IV & SC	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

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

- Cimzia (certolizumab pegol)
- Taltz (ixekizumab)
- Rinvoq (upadacitinib)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

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

Product Name: 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 - Paid claims or submission of medical records (e.g., chart notes) confirming a 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	Enthesitis-Related Arthritis (ERA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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 - Paid claims or submission of medical records (e.g., chart notes) confirming a 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	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

AND

2 - Prescribed by or in consultation with a dermatologist

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 one formulary adalimumab product

OR

3.2 Both of the following:

3.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

3.2.2 Documentation of positive clinical response to therapy

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary adalimumab 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

Product Name: Cosentyx SC	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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

AND

2 - Prescribed by or in consultation with a dermatologist

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 one formulary adalimumab product

OR

3.2 Both of the following:

3.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

3.2.2 Documentation of positive clinical response to therapy

Notes	* For review process only: Refer to the table in the Background sectio n for carrier-specific formulary adalimumab products

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products: Adalimumab-adaz Hyrimoz Hadlima Adalimumab-fkjp

4 . References

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.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160838
Guideline Name	Cotellic (cobimetinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cotellic (cobimetinib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. **Histiocytic Neoplasms** Indicated as a single agent for the treatment of adult patients with histiocytic neoplasms.

2 . Criteria

Product Name: Cotellic	
Diagnosis	Melanoma

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

Product Name	Generic Name	GPI	Brand/Generic
COTELLIC	COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)	21533530200320	Brand

Approval Criteria

1 - Diagnosis of unresectable or metastatic melanoma

AND

2 - One of the following: [A]

2.1 Patient has a BRAF V600E mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

2.2 Patient has a BRAF V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Used in combination with Zelboraf (vemurafenib)*

Notes	*This product may require prior authorization.

Product Name: Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COTELLIC	COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)	21533530200320	Brand

Approval Criteria

1 - Diagnosis of histiocytic neoplasm

AND

2 - Used as monotherapy

Product Name: Cotellic	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COTELLIC	COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)	21533530200320	Brand

Approval Criteria

1 - Patient has not experienced disease progression while on therapy

3 . Endnotes

A. The cobas 4800 BRAF V600 Mutation Test is an FDA approved option and was used in the pivotal trial. [2, 3] The cobas 4800 BRAF V600 Mutation Test is also listed as the FDA approved companion diagnostic device for Zelboraf (vemurafenib). [3]

4 . References

1. Cotellic Prescribing Information. Genentech USA, Inc. South San Francisco, CA. May 2023.
2. Larkin J, Ascierto PA, Dréno B, et al. Combined vemurafenib and cobimetinib in BRAF-mutated melanoma. N Engl J Med. 2014;371(20):1867-76.
3. U.S. Food and Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm. Accessed May 23, 2024.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160839
Guideline Name	Coverage of Off-Label Non-FDA Approved Indications
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication	
Diagnosis	Off-label non-cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Off-label use			
Non-FDA approved use			
non-fda			

off-label			
off			

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [1]

OR

1.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [1]

OR

1.3 The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Diagnosis	Off-label cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Off-label use			
Non-FDA approved use			
non-fda			

off-label			
off			

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in AHFS DI [2]

OR

1.2 Diagnosis is supported as a use in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, A]

OR

1.3 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, B]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation

- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

OR

1.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

2 . Background

Clinical Practice Guidelines

DRUGDEX Strength of Recommendation [6]

Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been

		proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
Class Indeterminate	Evidence Inconclusive	

NCCN Categories of Evidence and Consensus [A]

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consens the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.
Against proposed off-label use	The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence).

	Additional studies are necessary to define the role of this medication for the off-label use.

Level of Evidence Scale for Oncology Off-Label Use

A	**Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.**
B	**Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.**
C	**Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.**
G	**Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.**

3 . Endnotes

A. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]
B. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally

considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed September 20, 2023.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed September 20, 2023.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed September 20, 2023.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-00443O. Available at: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=31#decision. Accessed September 20, 2023.
5. Wolters Kluwer Clinical Drug Information's Request for CMS evaluation of Lexi-Drugs as a compendium for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens. Available at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/covdoc31.pdf. Accessed September 20, 2023.
6. Micromedex Healthcare Series. Recommendation, Evidence, and Efficacy Ratings. https://www.micromedexsolutions.com/micromedex2/librarian/CS/8F8397/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/136D2F/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=3198&contentSetId=50&title=Recommendation%2C+Evidence+and+Efficacy+Ratings&servicesTitle=Recommendation%2C+Evidence+and+Efficacy+Ratings. Accessed September 20, 2023.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160840
Guideline Name	Daliresp (roflumilast)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Daliresp (roflumilast)
Chronic obstructive pulmonary disorder (COPD) Indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Limitations of Use: Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm. Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

2 . Criteria

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DALIRESP	ROFLUMILAST TAB 500 MCG	44450065000320	Brand
DALIRESP	ROFLUMILAST TAB 250 MCG	44450065000310	Brand
ROFLUMILAST	ROFLUMILAST TAB 250 MCG	44450065000310	Generic
ROFLUMILAST	ROFLUMILAST TAB 500 MCG	44450065000320	Generic

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD) [A, B]

AND

2 - History of COPD exacerbations which require the use of systemic corticosteroids, antibiotics, or hospital admission [C]

AND

3 - Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g., Combivent, Spiriva)

AND

4 - Trial and failure or intolerance to generic roflumilast (Applies to brand Daliresp only)

Notes	Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DALIRESP	ROFLUMILAST TAB 500 MCG	44450065000320	Brand
ROFLUMILAST	ROFLUMILAST TAB 250 MCG	44450065000310	Generic
ROFLUMILAST	ROFLUMILAST TAB 500 MCG	44450065000320	Generic
DALIRESP	ROFLUMILAST TAB 250 MCG	44450065000310	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and failure or intolerance to generic roflumilast (Applies to brand Daliresp only)

Notes	Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

3 . Endnotes

A. Patients enrolled in the pivotal trials had a forced expiratory volume in 1 second [FEV1] less than or equal to 50% of predicted and FEV1/forced vital capacity [FVC] less than 0.7). [1-3]
B. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) treatment guidelines, moderate COPD is defined as FEV1 less than 80% but greater than or equal to 50%; severe COPD is defined as FEV1 less than 50% but greater than or equal to 30%; and very severe COPD is defined as FEV1 less than 30%. [4]
C. In the pivotal studies the rate of moderate exacerbations was defined as requiring intervention with systemic glucocorticosteroids. Severe exacerbations were defined as leading to hospitalization and/or to death. [1]

4 . References

1. Daliresp Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. March 2020.
2. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): IBM Corporation.; Updated periodically. Available by subscription at: https://www.micromedexsolutions.com/. Accessed August 24, 2021.

3. FDA Summary Review. Accessed at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022522Orig1s000SumR.pdf. Accessed August 24, 2021.
4. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2023 report). Accessed at: file:///C:/Users/hfatani/Downloads/GOLD-2023-ver-1.3-17Feb2023_WMV.pdf. Accessed August 7, 2023.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160841
Guideline Name	Daraprim (pyrimethamine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Daraprim (pyrimethamine)
Treatment of toxoplasmosis Indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

2 . Criteria

Product Name: Brand Daraprim, generic pyrimethamine	
Diagnosis	Toxoplasmosis
Approval Length	12 Months [A, B]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARAPRIM	PYRIMETHAMINE TAB 25 MG	13000040000310	Brand
PYRIMETHAMINE	PYRIMETHAMINE TAB 25 MG	13000040000310	Generic

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Patient is using pyrimethamine for one of the following: [2, 3]

- Active treatment of toxoplasmosis (e.g., toxoplasmic encephalitis, ocular toxoplasmosis)
- Secondary prophylaxis of toxoplasmosis
- Treatment of congenital toxoplasmosis

OR

1.1.2 All of the following: [2]

1.1.2.1 Patient is using pyrimethamine for primary prophylaxis of toxoplasmosis

AND

1.1.2.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.1.2.3 One of the following:

1.1.2.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.1.2.3.2 Evidence of life-threatening reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g., toxic epidermal necrolysis [TEN], Stevens-Johnson syndrome)

AND

1.2 Prescribed by or in consultation with an infectious disease specialist

Product Name: Brand Daraprim, generic pyrimethamine	
Diagnosis	Malaria (off-label)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARAPRIM	PYRIMETHAMINE TAB 25 MG	13000040000310	Brand
PYRIMETHAMINE	PYRIMETHAMINE TAB 25 MG	13000040000310	Generic

Approval Criteria

1 - Requests for coverage of any pyrimethamine products for the treatment and/or prophylaxis of malaria are not authorized and will not be approved. The use of pyrimethamine for the treatment and/or prophylaxis of malaria is not recommended by the Centers for Disease Control and Prevention (CDC) [5]

3 . Endnotes

A. Prescriber should consider discontinuation of primary prophylaxis if CD4 is greater than 200 cells/mm3 for more than 3 months after institution of combination antiretroviral therapy. [2]
B. Prescriber should consider discontinuation of secondary prophylaxis if CD4 is greater than 200 cells/mm3 for more than 6 months after institution of combination antiretroviral therapy. [2]

4 . References

1. Daraprim Prescribing Information. Vyera Pharmaceuticals. New York, NY. August 2017.

2. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/treatment-hiv-associated. Accessed May 27, 2024.
3. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/pediatric-oi/tables-pediatric-oi.pdf. Accessed May 27, 2024.
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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160842
Guideline Name	Darzalex (daratumumab), Darzalex Faspro (daratumumab and hyaluronidase-fihj) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Darzalex (daratumumab)
Multiple Myeloma - Monotherapy Indicated as monotherapy, for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. **Multiple Myeloma - Combination therapy** Indicated in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. **Multiple Myeloma - Combination therapy** Indicated in combination with carfilzomib and dexamethasone in adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. **Multiple Myeloma - Combination therapy** Indicated in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received

at least two prior therapies including lenalidomide and a proteasome inhibitor.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, melphalan, and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, thalidomide, and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.

Drug Name: Darzalex Faspro (daratumumab and hyaluronidase-fihj)

Multiple Myeloma - Monotherapy Indicated as monotherapy, for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

Multiple Myeloma - Combination Indicated in combination with lenalidomide and dexamethasone or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

Multiple Myeloma - Combination Indicated in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor.

Multiple Myeloma - Combination Indicated in combination with carfilzomib and dexamethasone in adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.

Newly Diagnosed Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, thalidomide, and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant.

Light Chain (AL) Amyloidosis Indicated in combination with bortezomib, cyclophosphamide,

and dexamethasone for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Limitations of Use: DARZALEX FASPRO is not indicated and is not recommended for the treatment of patients with light chain (AL) amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.

2 . Criteria

Product Name: Darzalex	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX	DARATUMUMAB IV SOLN 100 MG/5ML	21354027002020	Brand
DARZALEX	DARATUMUMAB IV SOLN 400 MG/20ML	21354027002030	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name: Darzalex	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX	DARATUMUMAB IV SOLN 100 MG/5ML	21354027002020	Brand
DARZALEX	DARATUMUMAB IV SOLN 400 MG/20ML	21354027002030	Brand

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Used in combination with both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

Product Name: Darzalex Faspro	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name: Darzalex Faspro	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

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

AND

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

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name: Darzalex Faspro	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Used in combination with both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 One of the following:

2.2.2.1 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

OR

2.2.2.2 Used in combination with all of the following: (2)

- bortezomib
- lenalidomide
- dexamethasone

Product Name: Darzalex Faspro	
Diagnosis	Newly Diagnosed Multiple Myeloma

Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming newly diagnosed multiple myeloma

AND

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

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Used in combination with both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 One of the following:

2.2.2.1 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

OR

2.2.2.2 Used in combination with all of the following: (2)

- bortezomib
- lenalidomide
- dexamethasone

Product Name: Darzalex Faspro	
Diagnosis	Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Newly diagnosed light chain (AL) amyloidosis

AND

2 - Used in combination with ALL of the following:

- Bortezomib
- Cyclophosphamide
- Dexamethasone

AND

3 - All of the following: [3]

- Patient does not have New York Heart Association (NYHA) Class IIIB disease
- Patient does not have New York Heart Association (NYHA) Class IV disease
- Patient does not have Mayo Stage IIIB disease

Product Name: Darzalex Faspro	
Diagnosis	Light Chain Amyloidosis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming newly diagnosed light chain (AL) amyloidosis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with ALL of the following:

- Bortezomib
- Cyclophosphamide
- Dexamethasone

AND

3 - All of the following: [3]

- Patient does not have New York Heart Association (NYHA) Class IIIB disease
- Patient does not have New York Heart Association (NYHA) Class IV disease
- Patient does not have Mayo Stage IIIB disease

Product Name: Darzalex, Darzalex Faspro	
Diagnosis	All Indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ INJ 1800-30000 MG-UNIT/15ML	21990002152020	Brand
DARZALEX	DARATUMUMAB IV SOLN 100 MG/5ML	21354027002020	Brand
DARZALEX	DARATUMUMAB IV SOLN 400 MG/20ML	21354027002030	Brand

Approval Criteria

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

3 . References

1. Darzalex Prescribing Information. Janssen Biotech, Inc. Horsham, PA. January 2023.

2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Multiple Myeloma v4.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August 13, 2024
3. Darzalex Faspro Prescribing Information. Janssen Biotech, Inc. Horsham, PA. July 2024.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160843
Guideline Name	Deferasirox products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Exjade (deferasirox), deferasirox tablet, Jadenu (deferasirox), Jadenu Sprinkle (deferasirox)
Chronic Iron Overload Due to Blood Transfusions (Transfusional Iron Overload) Indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. Limitations of Use: The safety and efficacy of deferasirox when administered with other iron chelation therapy have not been established. **Treatment of Chronic Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes** Indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L. Limitations of Use: The safety and efficacy of deferasirox when administered with other iron chelation therapy have not been established. **Off Label Uses: Myelodysplastic syndrome (MDS)** Low to intermediate risk

myelodysplastic syndrome (MDS) for management of iron overload and in potential transplant patients who have received more than 20 red blood cell transfusions [11]

2 . Criteria

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JADENU	DEFERASIROX TAB 90 MG	93100025000320	Brand
JADENU	DEFERASIROX TAB 180 MG	93100025000330	Brand
JADENU	DEFERASIROX TAB 360 MG	93100025000340	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Brand

Approval Criteria

1 - Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has a baseline ferritin level more than 1,000 mcg/L

AND

4 - Patient has required the transfusion of at least 100 mL/kg packed red blood cells

AND

5 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Generic
DEFERASIROX	DEFERASIROX TAB 90 MG	93100025000320	Generic
DEFERASIROX	DEFERASIROX TAB 360 MG	93100025000340	Generic
DEFERASIROX	DEFERASIROX TAB 180 MG	93100025000330	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Generic

Approval Criteria

1 - Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has a baseline ferritin level more than 1,000 mcg/L

AND

4 - Patient has required the transfusion of at least 100 mL/kg packed red blood cells

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JADENU	DEFERASIROX TAB 90 MG	93100025000320	Brand
JADENU	DEFERASIROX TAB 180 MG	93100025000330	Brand
JADENU	DEFERASIROX TAB 360 MG	93100025000340	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Brand

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient has Low or Intermediate-1 disease or is a potential transplant patient

AND

3 - Patient has received more than 20 red blood cell transfusions

AND

4 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Generic
DEFERASIROX	DEFERASIROX TAB 90 MG	93100025000320	Generic
DEFERASIROX	DEFERASIROX TAB 360 MG	93100025000340	Generic
DEFERASIROX	DEFERASIROX TAB 180 MG	93100025000330	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Generic

DEFERASIROX	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Generic

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient has Low or Intermediate-1 disease or is a potential transplant patient

AND

3 - Patient has received more than 20 red blood cell transfusions

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis) & Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JADENU	DEFERASIROX TAB 90 MG	93100025000320	Brand
JADENU	DEFERASIROX TAB 180 MG	93100025000330	Brand
JADENU	DEFERASIROX TAB 360 MG	93100025000340	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Brand

Approval Criteria

1 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

AND

2 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis) & Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Generic
DEFERASIROX	DEFERASIROX TAB 90 MG	93100025000320	Generic
DEFERASIROX	DEFERASIROX TAB 360 MG	93100025000340	Generic
DEFERASIROX	DEFERASIROX TAB 180 MG	93100025000330	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Generic

Approval Criteria

1 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JADENU	DEFERASIROX TAB 90 MG	93100025000320	Brand
JADENU	DEFERASIROX TAB 180 MG	93100025000330	Brand
JADENU	DEFERASIROX TAB 360 MG	93100025000340	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Brand

Approval Criteria

1 - Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

AND

2 - Patient is 10 years of age or older

AND

3 - Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher

AND

4 - Serum ferritin level greater than 300 mcg/L

AND

5 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Generic
DEFERASIROX	DEFERASIROX TAB 90 MG	93100025000320	Generic
DEFERASIROX	DEFERASIROX TAB 360 MG	93100025000340	Generic
DEFERASIROX	DEFERASIROX TAB 180 MG	93100025000330	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Generic

Approval Criteria

1 - Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

AND

2 - Patient is 10 years of age or older

AND

3 - Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher

AND

4 - Serum ferritin level greater than 300 mcg/L

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JADENU	DEFERASIROX TAB 90 MG	93100025000320	Brand
JADENU	DEFERASIROX TAB 180 MG	93100025000330	Brand
JADENU	DEFERASIROX TAB 360 MG	93100025000340	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Brand
EXJADE	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Brand
JADENU SPRINKLE	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Brand

Approval Criteria

1 - Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher

AND

2 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

AND

3 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 125 MG	93100025007320	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 250 MG	93100025007330	Generic
DEFERASIROX	DEFERASIROX TAB FOR ORAL SUSP 500 MG	93100025007340	Generic
DEFERASIROX	DEFERASIROX TAB 90 MG	93100025000320	Generic
DEFERASIROX	DEFERASIROX TAB 360 MG	93100025000340	Generic
DEFERASIROX	DEFERASIROX TAB 180 MG	93100025000330	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 90 MG	93100025003020	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 180 MG	93100025003030	Generic
DEFERASIROX	DEFERASIROX GRANULES PACKET 360 MG	93100025003040	Generic

Approval Criteria

1 - Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher

AND

2 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

3 . References

1. Exjade Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2020.
2. Cappellini MD, Cohen A, Piga A, et al. A Phase III study of deferasirox (ICL670), a once-daily oral iron chelator, in patients with [beta]-thalassemia. Blood. 2006;107(9):3455-62.
3. Cappellini MD. Iron-chelating therapy with the new oral agent ICL670 (Exjade). Best Pract Res Clin Haematol. 2005;18(2):289-98.
4. Galanello R, Piga A, Alberti D, Rouan MC, Bigler H, Sechaud R. Safety, tolerability, and pharmacokinetics of ICL670, a new orally active iron-chelating agent in patients with transfusion-dependent iron overload due to beta-thalassemia. J Clin Pharmacol. 2003;43(6):565-72.
5. Nisbet-Brown E, Olivieri NF, Giardina PJ, et al. Effectiveness and safety of ICL670 in iron-loaded patients with thalassaemia: a randomized, double-blind, placebo-controlled, dose-escalation trial. Lancet. 2003;361(9369):1597-602.
6. International Association of Sickle Cell Nurses and Physician Assistants. Nursing Practice Guidelines: Care of the Patient with Sickle Cell Disease and Iron Overload. 2008. http://www.iascnapa.org/guidelines/Guidelines_IronOverload.pdf. Accessed on April 8, 2021.
7. Ho PJ, Tay L, Linderman R, Catley L, Bowden DK. Australian guidelines for the assessment of iron overload and iron chelation in transfusion-dependent thalassaemia major, sickle cell disease and other congenital anaemias. Intern Med J. 2011;41(7):516-24.
8. Angelucci E, Barosi G, Camaschella C, et al. Italian Society of Hematology practice guidelines for the management of iron overload in thalassemia major and related disorders. Haematologica. 2008;93(5):741-52.
9. Porter JB and Shah FT. Iron overload in thalassemia and related conditions: therapeutic goals and assessment of response to chelation therapies. 2010 Dec;24(6):1109-30.
10. Jadenu, Jadenu Sprinkle Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. July 2020.
11. AHFS Drug Information (Adult and Pediatric) [Internet database]. Bethesda, Maryland. Lexicomp, Inc. Updated periodically. Available by subscription at: http://online.lexi.com/. Accessed on April 8, 2021.
12. Deferasirox tablet Prescribing Information. Cipla USA, Inc. Warren, NJ. August 2020.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160844
Guideline Name	Demser (metyrosine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Demser (metyrosine)
Pheochromocytoma Indicated for the treatment of patients with pheochromocytoma for preoperative preparation of patients for surgery, management of patients when surgery is contraindicated, and chronic treatment of patients with malignant pheochromocytoma. Metyrosine capsules are not recommended for the control of essential hypertension.

2 . Criteria

Product Name: Brand Demser, generic metyrosine	
Diagnosis	Preoperative preparation
Approval Length	1 Time(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
METYROSINE	METYROSINE CAP 250 MG	36300025000110	Generic
DEMSER	METYROSINE CAP 250 MG	36300025000110	

Approval Criteria

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing:

- plasma free metanephrines
- urinary fractioned metanephrines

AND

2 - Medication is being used for preoperative preparation

AND

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

- alpha-adrenergic blocker (e.g., phenoxybenzamine, doxazosin, terazosin)
- beta-adrenergic blocker (e.g., propranolol, metoprolol)

AND

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

- Endocrinologist
- Endocrine surgeon

Product Name: Brand Demser, generic metyrosine	
Diagnosis	Treatment of pheochromocytoma
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
METYROSINE	METYROSINE CAP 250 MG	36300025000110	Generic
DEMSER	METYROSINE CAP 250 MG	36300025000110	

Approval Criteria

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing:

- plasma free metanephrines
- urinary fractioned metanephrines

AND

2 - Patient with hormonally active (catecholamine excess) pheochromocytoma

AND

3 - One of the following:

3.1 Patient is not a candidate for surgery

OR

3.2 Chronic treatment due to malignant pheochromocytoma

AND

4 - Patient has not reached normotension after treatment with a selective alpha-1-adrenergic blocker (e.g., doxazosin, terazosin) and beta-adrenergic blocker (e.g., propranolol, metoprolol)

AND

5 - Medication will not be used to control essential hypertension

AND

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

- Endocrinologist
- Provider who specializes in the management of pheochromocytoma

Product Name: Brand Demser, generic metyrosine	
Diagnosis	Treatment of pheochromocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
METYROSINE	METYROSINE CAP 250 MG	36300025000110	Generic
DEMSER	METYROSINE CAP 250 MG	36300025000110	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decreased frequency and severity of hypertensive attacks)

3 . References

1. Metyrosine Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. November 2020.
2. Naruse M, Satoh F, Tanabe A, et al. Efficacy and safety of metyrosine in pheochromocytoma/paraganglioma: a multi-center trial in Japan. Endocrine Journal. 2018;65(3):359-371.

3. Lenders JWM, Duh Q-Y, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism. 2014;99(6):1915-1942.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160450
Guideline Name	Diabetic GLP-1 Agonists
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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*,**, Brand 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 necessity and do not review for off-label use. **If patient meets criteria above, please approve at GPI-10.

Product Name: Byetta*, Bydureon BCise*, Mounjaro*, Trulicity*, Brand Brand 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.

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

Prior Authorization Guideline

Guideline ID	GL-160845
Guideline Name	Diacomit (stiripentol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Diacomit (stiripentol)
Dravet syndrome (DS) Indicated for the treatment of seizures associated with Dravet syndrome in patients taking clobazam who are 6 months of age or older and weighing 7 kg or more.There are no clinical data to support the use of DIACOMIT as monotherapy in Dravet syndrome.

2 . Criteria

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

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIACOMIT	STIRIPENTOL CAP 250 MG	72600070000120	Brand
DIACOMIT	STIRIPENTOL CAP 500 MG	72600070000130	Brand
DIACOMIT	STIRIPENTOL PACKET 250 MG	72600070003020	Brand
DIACOMIT	STIRIPENTOL PACKET 500 MG	72600070003030	Brand

Approval Criteria

1 - Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2 - Used in combination with clobazam

AND

3 - BOTH of the following:

- Patient is 6 months of age or older
- Patient weighs 7kg or more

AND

4 - Prescribed by or in consultation with a neurologist

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

Product Name	Generic Name	GPI	Brand/Generic

DIACOMIT	STIRIPENTOL CAP 250 MG	72600070000120	Brand
DIACOMIT	STIRIPENTOL CAP 500 MG	72600070000130	Brand
DIACOMIT	STIRIPENTOL PACKET 250 MG	72600070003020	Brand
DIACOMIT	STIRIPENTOL PACKET 500 MG	72600070003030	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Used in combination with clobazam

3 . References

1. Diacomit Prescribing Information. Biocodex. Gentilly, France. July 2022.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160846
Guideline Name	Dibenzyline (phenoxybenzamine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Dibenzyline (phenoxybenzamine)
Pheochromocytoma Indicated in the treatment of pheochromocytoma to control episodes of hypertension and swelling.

2 . Criteria

Product Name: Brand Dibenzyline, generic phenoxybenzamine	
Diagnosis	Pheochromocytoma
Approval Length	1 Time(s) [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PHENOXYBENZAMINE HYDROCHLORIDE	PHENOXYBENZAMINE HCL CAP 10 MG	36300010100105	Generic
DIBENZYLINE	PHENOXYBENZAMINE HCL CAP 10 MG	36300010100105	Brand

Approval Criteria

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: [2]

- plasma free metanephrines
- urinary fractioned metanephrines

AND

2 - Medication is being used for preoperative preparation [A,1]

AND

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

- doxazosin
- terazosin
- prazosin

AND

4 - Treatment will also include a high-sodium diet and fluid intake [B]

AND

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

- Endocrinologist
- Endocrine surgeon

3 . Endnotes

A. Phenoxybenzamine is most commonly used for preoperative control of blood pressure. Its only current clinical use is in preparing patients with pheochromocytoma for surgery. [1]
B. Retrospective studies report that initiation of high-sodium diet a few days after the start of alpha-adrenergic receptor blockade reverses blood volume contraction, prevents orthostatic hypotension before surgery, and reduces the risk of significant hypotension after surgery. [2]

4 . References

1. Farrugia F, Martikos G, Tzanetis P, et al. Pheochromocytoma, diagnosis and treatment: Review of the literature. Endocrine Regulations. 2017;51(3):168-181.
2. Lenders JWM, Duh Q-Y, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism. 2014;99(6):1915-1942.
3. Phenoxybenzamine Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. July 2023.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160847
Guideline Name	Dichlorphenamide Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 - One of the following:

6.1 If new to therapy, dose will be initiated at 50mg twice daily

OR

6.2 Medication is being prescribed as continuation of therapy

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]

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-158683
Guideline Name	DPP-4 Inhibitors - ST, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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: Onglyza (saxagliptin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis, as it would not be effective in these settings.
Drug Name: Tradjenta (linagliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Not recommended in patients with type 1 diabetes mellitus as it would not be effective., 2) Has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using TRADJENTA.
Drug Name: Jentadueto (linagliptin/metformin), Jentadueto XR (linagliptin/metformin extended-release)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Not recommended in patients with type 1 diabetes mellitus., 2) Has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using JENTADUETO.
Drug Name: Kazano (alogliptin/metformin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Not recommended for use in patients with type 1 diabetes mellitus.
Drug Name: Kombiglyze XR (saxagliptin/metformin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate. Limitations of use: Not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
Drug Name: Nesina (alogliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Not recommended for use in patients with type 1 diabetes.
Drug Name: Oseni (alogliptin/pioglitazone)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Should not be used in patients with type 1 diabetes mellitus.
Drug Name: Zituvio (sitagliptin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) not recommended in patients with type 1 diabetes mellitus, 2) has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using ZITUVIO.

2 . Criteria

Product Name: Januvia, Janumet, Janumet XR, Jentadueto, Jentadueto XR, Tradjenta	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
JANUMET	SITAGLIPTIN-METFORMIN HCL TAB 50-500 MG	27992502700320	Brand
JANUMET	SITAGLIPTIN-METFORMIN HCL TAB 50-1000 MG	27992502700340	Brand
JANUMET XR	SITAGLIPTIN-METFORMIN HCL TAB ER 24HR 50-500 MG	27992502707520	Brand
JANUMET XR	SITAGLIPTIN-METFORMIN HCL TAB ER 24HR 50-1000 MG	27992502707530	Brand
JANUMET XR	SITAGLIPTIN-METFORMIN HCL TAB ER 24HR 100-1000 MG	27992502707540	Brand
JANUVIA	SITAGLIPTIN PHOSPHATE TAB 25 MG (BASE EQUIV)	27550070100320	Brand
JANUVIA	SITAGLIPTIN PHOSPHATE TAB 50 MG (BASE EQUIV)	27550070100330	Brand
JANUVIA	SITAGLIPTIN PHOSPHATE TAB 100 MG (BASE EQUIV)	27550070100340	Brand
TRADJENTA	LINAGLIPTIN TAB 5 MG	27550050000320	Brand
JENTADUETO	LINAGLIPTIN-METFORMIN HCL TAB 2.5-500 MG	27992502400320	Brand
JENTADUETO	LINAGLIPTIN-METFORMIN HCL TAB 2.5-850 MG	27992502400330	Brand
JENTADUETO	LINAGLIPTIN-METFORMIN HCL TAB 2.5-1000 MG	27992502400340	Brand
JENTADUETO XR	LINAGLIPTIN-METFORMIN HCL TAB ER 24HR 2.5-1000 MG	27992502407520	Brand
JENTADUETO XR	LINAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-1000 MG	27992502407530	Brand

Approval Criteria

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

AND

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

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

Product Name: Kazano, Brand Alogliptin/Metformin, Brand Kombiglyze XR , Generic saxagliptin/metformin ER, Nesina, Alogliptin, Brand Onglyza, Generic saxagliptin, Oseni, Alogliptin/Pioglitazone, Zituvio, Brand Sitagliptin, Brand Sitagliptin/Metformin

Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
KAZANO	ALOGLIPTIN-METFORMIN HCL TAB 12.5-500 MG	27992502100320	Generic
ALOGLIPTIN/METFORMIN HCL	ALOGLIPTIN-METFORMIN HCL TAB 12.5-500 MG	27992502100320	Generic
KAZANO	ALOGLIPTIN-METFORMIN HCL TAB 12.5-1000 MG	27992502100330	Generic
ALOGLIPTIN/METFORMIN HCL	ALOGLIPTIN-METFORMIN HCL TAB 12.5-1000 MG	27992502100330	Generic
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 2.5-1000 MG	27992502607520	Brand
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-500 MG	27992502607530	Brand
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-1000 MG	27992502607540	Brand
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 6.25 MG (BASE EQUIV)	27550010100310	Generic

NESINA	ALOGLIPTIN BENZOATE TAB 6.25 MG (BASE EQUIV)	27550010100310	Generic
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 12.5 MG (BASE EQUIV)	27550010100320	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 12.5 MG (BASE EQUIV)	27550010100320	Generic
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 25 MG (BASE EQUIV)	27550010100330	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 25 MG (BASE EQUIV)	27550010100330	Generic
ONGLYZA	SAXAGLIPTIN HCL TAB 2.5 MG (BASE EQUIV)	27550065100320	Brand
ONGLYZA	SAXAGLIPTIN HCL TAB 5 MG (BASE EQUIV)	27550065100330	Brand
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-15 MG	27994002100320	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-15 MG	27994002100320	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-30 MG	27994002100325	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-30 MG	27994002100325	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-45 MG	27994002100330	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-45 MG	27994002100330	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-15 MG	27994002100340	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-15 MG	27994002100340	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-30 MG	27994002100345	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-30 MG	27994002100345	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-45 MG	27994002100350	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-45 MG	27994002100350	Generic
SAXAGLIPTIN HYDROCHLORIDE	SAXAGLIPTIN HCL TAB 2.5 MG (BASE EQUIV)	27550065100320	Generic
SAXAGLIPTIN HYDROCHLORIDE	SAXAGLIPTIN HCL TAB 5 MG (BASE EQUIV)	27550065100330	Generic
SAXAGLIPTIN HYDROCHLORIDE/METFORMIN HYDROCHLORIDE ER	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 2.5-1000 MG	27992502607520	Generic

SAXAGLIPTIN HYDROCHLORIDE/METFORMIN HYDROCHLORIDE ER	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-1000 MG	27992502607540	Generic
SAXAGLIPTIN HYDROCHLORIDE/METFORMIN HYDROCHLORIDE ER	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-500 MG	27992502607530	Generic
ZITUVIO	SITAGLIPTIN TAB 25 MG	27550070000320	Brand
ZITUVIO	SITAGLIPTIN TAB 50 MG	27550070000330	Brand
ZITUVIO	SITAGLIPTIN TAB 100 MG	27550070000340	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 25 MG	27550070000320	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 50 MG	27550070000330	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 100 MG	27550070000340	Brand
SITAGLIPTIN/METFORMIN HYDROCHLORIDE	SITAGLIPTIN FREE BASE-METFORMIN HCL TAB 50-500 MG	27992502690320	Brand
SITAGLIPTIN/METFORMIN HYDROCHLORIDE	SITAGLIPTIN FREE BASE-METFORMIN HCL TAB 50-1000 MG	27992502690330	Brand

Approval Criteria

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

AND

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

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

AND

3 - Trial and failure of a minimum 90 day supply, intolerance, or contraindication to any one of the following preferred brands:

- Januvia
- Janumet
- Janumet XR

AND

4 - Trial and failure of a minimum 90 day supply, intolerance, or contraindication to any one of the following preferred brands:

- Jentadueto
- Jentadueto XR
- Tradjenta

Product Name: Kazano, Brand Alogliptin/Metformin, Brand Kombiglyze XR, Nesina, Alogliptin, Brand Onglyza, Oseni, Alogliptin/Pioglitazone, Zituvio, Brand Sitagliptin	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
KAZANO	ALOGLIPTIN-METFORMIN HCL TAB 12.5-500 MG	27992502100320	Generic
ALOGLIPTIN/METFORMIN HCL	ALOGLIPTIN-METFORMIN HCL TAB 12.5-500 MG	27992502100320	Generic
KAZANO	ALOGLIPTIN-METFORMIN HCL TAB 12.5-1000 MG	27992502100330	Generic
ALOGLIPTIN/METFORMIN HCL	ALOGLIPTIN-METFORMIN HCL TAB 12.5-1000 MG	27992502100330	Generic
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 2.5-1000 MG	27992502607520	Brand
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-500 MG	27992502607530	Brand
KOMBIGLYZE XR	SAXAGLIPTIN-METFORMIN HCL TAB ER 24HR 5-1000 MG	27992502607540	Brand
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 6.25 MG (BASE EQUIV)	27550010100310	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 6.25 MG (BASE EQUIV)	27550010100310	Generic
ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 12.5 MG (BASE EQUIV)	27550010100320	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 12.5 MG (BASE EQUIV)	27550010100320	Generic

ALOGLIPTIN	ALOGLIPTIN BENZOATE TAB 25 MG (BASE EQUIV)	27550010100330	Generic
NESINA	ALOGLIPTIN BENZOATE TAB 25 MG (BASE EQUIV)	27550010100330	Generic
ONGLYZA	SAXAGLIPTIN HCL TAB 2.5 MG (BASE EQUIV)	27550065100320	Brand
ONGLYZA	SAXAGLIPTIN HCL TAB 5 MG (BASE EQUIV)	27550065100330	Brand
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-15 MG	27994002100320	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-15 MG	27994002100320	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-30 MG	27994002100325	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-30 MG	27994002100325	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-45 MG	27994002100330	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 12.5-45 MG	27994002100330	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-15 MG	27994002100340	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-15 MG	27994002100340	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-30 MG	27994002100345	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-30 MG	27994002100345	Generic
ALOGLIPTIN/PIOGLITAZONE	ALOGLIPTIN-PIOGLITAZONE TAB 25-45 MG	27994002100350	Generic
OSENI	ALOGLIPTIN-PIOGLITAZONE TAB 25-45 MG	27994002100350	Generic
ZITUVIO	SITAGLIPTIN TAB 25 MG	27550070000320	Brand
ZITUVIO	SITAGLIPTIN TAB 50 MG	27550070000330	Brand
ZITUVIO	SITAGLIPTIN TAB 100 MG	27550070000340	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 25 MG	27550070000320	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 50 MG	27550070000330	Brand
SITAGLIPTIN	SITAGLIPTIN TAB 100 MG	27550070000340	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure of a minimum 30 day supply, intolerance, or contraindication to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

AND

3 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure of a minimum 90 day supply, intolerance, or contraindication to any one of the following preferred brands:

- Januvia
- Janumet
- Janumet XR

AND

4 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure of a minimum 90 day supply, intolerance, or contraindication to any one of the following preferred brands:

- Jentadueto
- Jentadueto XR
- Tradjenta

3 . References

1. Januvia Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2023.
2. Janumet Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2022.

3. Onglyza Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. October 2019.
4. Tradjenta Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.
5. Janumet XR Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2022.
6. Jentadueto Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.
7. Jentadueto XR Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.
8. Oseni Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. December 2023.
9. Kazano Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. July 2023.
10. Nesina Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. July 2023.
11. Kombiglyze XR Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. October 2019.
12. Saxaglipitin hydrochloride/metformin hydrochloride ER Prescribing Information . Dr. Reddys Laboratories Princeton, NJ. January 2023
13. Saxaglipitin hydrochloride/metformin hydrochloride ER Prescribing Information . Aurobindo Pharma USA, Inc. East Windsor, NJ. April 2023
14. Zituvio Prescribing Information. Zydus Lifesciences Limited, Pharmez, Matoda, Amedabad, India. November 2023.

Prior Authorization Guideline

Guideline ID	GL-160848
Guideline Name	Duexis (ibuprofen and famotidine) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Duexis (ibuprofen/famotidine)
Osteoarthritis, rheumatoid arthritis, and gastrointestinal ulcers Indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and /or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. Controlled trials do not extend beyond 6 months.

2 . Criteria

Product Name: Brand Duexis, generic ibuprofen-famotidine F

Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUEXIS	IBUPROFEN-FAMOTIDINE TAB 800-26.6 MG	66109902320340	Brand
IBUPROFEN/FAMOTIDINE	IBUPROFEN-FAMOTIDINE TAB 800-26.6 MG	66109902320340	Generic

Approval Criteria

1 - One of the following diagnoses:

- Osteoarthritis
- Rheumatoid Arthritis

AND

2 - One of the following [2]:

- History of peptic ulcer disease
- History of gastrointestinal (GI) bleeding, obstruction, or perforation
- Erosive esophagitis
- Used in combination with aspirin

AND

3 - History of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generics:

- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam

- sulindac
- tolmetin
- diclofenac

AND

4 - History of a minimum 30 day trial and failure, or intolerance to two of the following generic H2-receptor antagonists:

- cimetidine
- famotidine
- nizatidine
- ranitidine

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with brand Duexis or generic ibuprofen-famotidine instead of taking individual products in combination

Product Name: Brand Duexis, generic ibuprofen-famotidine NF	
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
DUEXIS	IBUPROFEN-FAMOTIDINE TAB 800-26.6 MG	66109902320340	Brand
IBUPROFEN/FAMOTIDINE	IBUPROFEN-FAMOTIDINE TAB 800-26.6 MG	66109902320340	Generic

Approval Criteria

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

- Osteoarthritis
- Rheumatoid Arthritis

AND

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

- History of peptic ulcer disease
- History of gastrointestinal (GI) bleeding, obstruction, or perforation
- Erosive esophagitis
- Used in combination with aspirin

AND

3 - Paid claims or submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generics:

- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam
- sulindac
- tolmetin
- diclofenac

AND

4 - Paid claims or submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generic H2-receptor antagonists:

- cimetidine
- famotidine
- nizatidine
- ranitidine

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with brand Duexis or generic ibuprofen-famotidine instead of taking individual products in combination

3 . References

1. Duexis [prescribing information]. Deerfield, IL: Horizon Medicines, LLC; April 2021.
2. Solomon C. Upper Gastrointestinal Bleeding Due to a Peptic Ulcer. N Engl J Med. 2016;374:2367-2376.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160849
Guideline Name	Dupixent (dupilumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 at least ONE of the following [2]:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

4 - Patient is 6 months of age or older

AND

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

- Dermatologist
- Allergist/Immunologist

Notes	*Product may require step therapy

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

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand

DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

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

- Reduction in BSA involvement from baseline
- Reduction in SCORAD index value from baseline [A]

Product Name: Dupixent	
Diagnosis	Eosinophilic Asthma
Approval Length	6 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of moderate to severe asthma

AND

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [C, D]

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [4, 5, 7]

OR

3.2 Prior asthma-related hospitalization within the past 12 months [4, 5, E]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Patient is 6 years of age or older but less than 12 years of age

AND

4.1.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1.2.1 Both of the following:

- Medium-dose inhaled corticosteroid (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.1.2.2 One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone

propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg])

OR

4.2 Both of the following:

4.2.1 Patient is 12 years of age or older

AND

4.2.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.2.2.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.2.2.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg])

AND

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

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Asthma

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

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications

AND

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

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Oral Corticosteroid Dependent Asthma
Approval Length	6 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of moderate to severe asthma

AND

2 - Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 6 years of age or older but less than 12 years of age

AND

3.1.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

3.1.2.1 Both of the following:

- Medium-dose inhaled corticosteroid (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

3.1.2.2 One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg])

OR

3.2 Both of the following:

3.2.1 Patient is 12 years of age or older

AND

3.2.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

3.2.2.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

3.2.2.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone

propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg])

AND

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

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Oral Corticosteroid Dependent Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], reduction in oral corticosteroid dose)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications

AND

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

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Chronic rhinosinusitis with nasal polyposis (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

AND

2 - Patient is 12 years of age or older

AND

2 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [8, 9]

AND

3 - Used in combination with another agent for CRSwNP [F]

AND

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

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Dupixent	
Diagnosis	Chronic rhinosinusitis with nasal polyposis (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NC; 0-3 scale])

AND

2 - Used in combination with another agent for CRSwNP [F]

AND

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

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand

Approval Criteria

1 - Diagnosis of eosinophilic esophagitis (EoE)

AND

2 - Patient has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, heartburn, abdominal pain) [13-15]

AND

3 - Patient has at least 15 intraepithelial eosinophils per high power field (HPF) [1, 13-15]

AND

4 - Other causes of esophageal eosinophilia have been excluded [13-15]

AND

5 - Both of the following:

- Patient is at least 1 year of age
- Patient weighs at least 15 kg

AND

6 - Trial and failure (of a minimum 8-week duration), contraindication, or intolerance to one of the following:

- Proton pump inhibitors (e.g., pantoprazole, omeprazole)
- Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone)

AND

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

- Gastroenterologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline [1, 13-15]:

- Symptoms (e.g., dysphagia, food impaction, heartburn, chest pain)
- Histologic measures (e.g., esophageal intraepithelial eosinophil count)
- Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures)

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of prurigo nodularis (PN)

AND

2 - Patient has at least 20 nodular lesions

AND

3 - Trial and failure, contraindication, or intolerance to one medium or higher potency topical corticosteroid [16, 17]

AND

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

- Allergist/Immunologist
- Dermatologist

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

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

- Reduction in the number of nodular lesions from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Dupixent	
Diagnosis	Chronic obstructive pulmonary disease (COPD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML	9027302000D515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML	9027302000D520	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML	9027302000E510	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML	9027302000E515	Brand
DUPIXENT	DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	9027302000E520	Brand

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2 - Presence of Type 2 inflammation evidenced by blood eosinophils greater than or equal to 300 cells per microliter at baseline

AND

3 - Patient is receiving one of the following therapies at maximally tolerated doses

- Triple therapy (i.e., an inhaled corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA) and a long-acting beta agonist (LABA)
- If ICS are contraindicated, a LAMA and a LABA

AND

4 - Patient has had one of the following within the past 12 months:

4.1 At least two exacerbations where systemic corticosteroids [intramuscular, intravenous, or oral (e.g., prednisone)] were required at least once

OR

4.2 COPD-related hospitalization

AND

5 - Patient experiences dyspnea during everyday activities (e.g., needs to stop for breath when walking on level ground) [G]

AND

6 - Prescribed by or in consultation with a pulmonologist

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 at an optimized dose:

- 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

3 - Prescribed by or in consultation with a pulmonologist

3 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05

High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [7]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High

Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country - specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [5] The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [5]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
-	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Beclometasone dipropionate (pMDI, extrafine particle, HFA)	50-100	> 100-200	> 200
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Budesonide (nebules)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle*, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50		n.a.
Fluticasone propionate (DPI)	50-100	> 100-200	> 200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	> 100-200	> 200
Mometasone furoate (pMDI, standard particle, HFA)	100		200

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply

potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [10, 11] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [12]
B. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy.
C. In AS Trial 2, reductions in exacerbations were significant in the subgroup of subjects with baseline blood eosinophils greater than or equal to 150 cells/mcL. In subjects with baseline blood eosinophil count less than 150 cells/mcL, similar severe exacerbation rates were observed between Dupixent and placebo. [1]
D. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [3]
E. Recommendation inferred from the national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.
F. Other agents used for CRSwNP include intranasal corticosteroids and nasal saline.
G. In the BOREAS trial, the inclusion criteria included a grade of greater than or equal to 2 on the Medical Research Council (MRC) Dyspnea Scale. [18,19]

5 . References

1. Dupixent Prescribing Information. Sanofi-aventis U.S. LLC. Bridgewater, NJ. January 2024.
2. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
3. Institute for Clinical and Economic Review (ICER). Biologic therapies for treatment of asthma associated with type 2 inflammation: effectiveness, value, and value-based price benchmarks. https://icer.org/wp-content/uploads/2020/10/ICER_Asthma-Final-Report_Unredacted_08122020.pdf. Published December 20, 2018. Accessed March 2, 2021.
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17. Leis M, Fleming P, Lynde CW. Prurigo nodularis: review and emerging treatments. Skin Therapy Lett. 2021;26(3):5-8.
18. BOREAS trial | Pivotal Study to Assess the Efficacy, Safety and Tolerability of Dupilumab in Patients With Moderate-to-severe COPD With Type 2 Inflammation | https://clinicaltrials.gov/study/NCT03930732
19. Modified Medical Research Council (mMRC) dyspnea scale | https://www.uptodate.com/contents/image?imageKey=PULM/86426

20. NOTUS trial | Pivotal Study to Assess the Efficacy, Safety and Tolerability of Dupilumab in Patients With Moderate to Severe COPD With Type 2 Inflammation | https://clinicaltrials.gov/study/NCT04456673?term=notus&rank=1

6 . Revision History

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

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-160850
Guideline Name	Emflaza (deflazacort) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 Documentation of a confirmed mutation of the dystrophin gene

OR

3.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

4 - Patient is 2 years of age or older

AND

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

AND

6 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

AND

7 - Patient has had a trial and failure or intolerance to prednisone or prednisolone given at a dose of 0.75 mg/kg/day or 10 mg/kg/weekend [B, 3-5]

AND

8 - One of the following:

8.1 Trial and intolerance to generic deflazacort tablet (Applies to Brand Emflaza tablet only)

OR

8.2 Trial and intolerance to generic deflazacort suspension (Applies to Brand Emflaza oral suspension only)

Product Name: Brand Emflaza, generic deflazacort	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EMFLAZA	DEFLAZACORT TAB 6 MG	22100017000340	Brand

EMFLAZA	DEFLAZACORT TAB 18 MG	22100017000350	Brand
EMFLAZA	DEFLAZACORT TAB 30 MG	22100017000360	Brand
EMFLAZA	DEFLAZACORT TAB 36 MG	22100017000365	Brand
EMFLAZA	DEFLAZACORT SUSP 22.75 MG/ML	22100017001830	Brand
DEFLAZACORT	DEFLAZACORT TAB 6 MG	22100017000340	Generic
DEFLAZACORT	DEFLAZACORT TAB 18 MG	22100017000350	Generic
DEFLAZACORT	DEFLAZACORT TAB 30 MG	22100017000360	Generic
DEFLAZACORT	DEFLAZACORT TAB 36 MG	22100017000365	Generic
DEFLAZACORT	DEFLAZACORT SUSP 22.75 MG/ML	22100017001830	Generic

Approval Criteria

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

AND

2 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

AND

3 - One of the following:

3.1 Trial and intolerance to generic deflazacort tablet (Applies to Brand Emflaza tablet only)

OR

3.2 Trial and intolerance to generic deflazacort suspension (Applies to Brand Emflaza oral suspension only)

Product Name: Brand Emflaza	
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

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) confirming diagnosis of Duchenne muscular dystrophy (DMD)

AND

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

AND

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

3.1 Documentation of a confirmed mutation of the dystrophin gene

OR

3.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

4 - Patient is 2 years of age or older

AND

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

AND

6 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

AND

7 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to prednisone or prednisolone given at a dose of 0.75 mg/kg/day or 10 mg/kg/weekend [B, 3-5]

AND

8 - One of the following:

8.1 Both of the following (Applies to Brand Emflaza tablet only):

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

AND

8.1.2 Submission of medical records (e.g., chart notes) confirming generic deflazacort tablet 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 tablet has not been shown to be effective despite having the same active ingredient

OR

8.2 Both of the following (Applies to Brand Emflaza suspension only):

8.2.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to generic deflazacort suspension

AND

8.2.2 Submission of medical records (e.g., chart notes) confirming generic deflazacort suspension has not been effective AND valid clinical rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when generic deflazacort suspension has not been shown to be effective despite having the same active ingredient

3 . Endnotes

A. Genetic testing after a positive biopsy diagnosis of Duchenne muscular dystrophy (DMD) is mandatory [2]. However a muscle biopsy is not necessary if a positive genetic diagnosis is confirmed first. In rare cases, when a genetic test has been done but no mutation has been found, a muscle biopsy is the next necessary step for patients who have increased creatine kinase concentrations and symptoms consistent with DMD.
B. Prednisone 0.75 mg/kg/d should be considered the optimal prednisone dose in DMD. Over 12 months, prednisone 10 mg/kg/weekend is equally effective, although long term outcomes of this alternative regimens are unknown [3].

4 . References

1. Emflaza Prescribing Information. PTC Therapeutics, Inc. South Plainfield, NJ. June 2021.
2. Bushby K, Finkel R, Birnkrant DJ, et al; DMD Care Considerations Working Group. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol. 2010;9(1):77-93.
3. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(5):465-72.
4. Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. Neurology. 2016 Nov 15;87(20):2123-2131.
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5 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160851
Guideline Name	Enbrel (etanercept)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Enbrel (etanercept)
Rheumatoid Arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Enbrel can be initiated in combination with methotrexate (MTX) or used alone. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older. **Psoriatic Arthritis (PsA)** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in adult patients with psoriatic arthritis. Enbrel can be used with or without MTX. Also indicated for the treatment of active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older. **Plaque Psoriasis (PsO)** Indicated for the treatment of patients 4 years or older with chronic

moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

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

2 . Criteria

Product Name: Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

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

- methotrexate
- leflunomide
- sulfasalazine

Product Name: Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

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

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

Product Name: Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

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

- leflunomide
- methotrexate

Product Name: Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)

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

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

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

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

Product Name: Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand

ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [5]:

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

AND

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

- Dermatologist
- Rheumatologist

Product Name: Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand

ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

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

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

Product Name: Enbrel	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - One of the following [6]:

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

AND

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

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Enbrel	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand

ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

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

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

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

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

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ENBREL SURECLICK	ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML	6629003000D530	Brand
ENBREL MINI	ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML	6629003000E230	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML	6629003000E525	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML	6629003000E530	Brand
ENBREL	ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML	66290030002015	Brand

Approval Criteria

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

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

3 . References

1. Enbrel Prescribing Information. Amgen. Thousand Oaks, CA. October 2023.

2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
7. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
8. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160852
Guideline Name	Epclusa (sofosbuvir/velpatasvir) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Epclusa (sofosbuvir and velpatasvir)
Chronic Hepatitis C (CHC) Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis, and with decompensated cirrhosis for use in combination with ribavirin.

2 . Criteria

Product Name: Epclusa*	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6

Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 200-50 MG	12359902650320	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 150-37.5 MG	12359902653020	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 200-50 MG	12359902653030	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes	*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 4, 5, or 6
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

5.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 4, 5, or 6
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2, 3
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2, 3
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does not have decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Epclusa*	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 200-50 MG	12359902650320	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 150-37.5 MG	12359902653020	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 200-50 MG	12359902653030	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes	*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Trial and failure or intolerance to Brand Epclusa

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

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

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Epclusa*

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 200-50 MG	12359902650320	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 150-37.5 MG	12359902653020	Brand
EPCLUSA	SOFOSBUVIR-VELPATASVIR PELLET PACK 200-50 MG	12359902653030	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes	*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - One of the following:

6.1 Trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - One of the following:

6.1 Trial and failure or intolerance to Brand Epclusa

OR

6.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SOFOSBUVIR/VELPATASVIR	SOFOSBUVIR-VELPATASVIR TAB 400-100 MG	12359902650330	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

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

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - One of the following:

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

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

1. Epclusa Prescribing Information. Gilead Science, Inc. Foster City, CA. April 2022.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160853
Guideline Name	Epidiolex (cannabidiol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Epidiolex (cannabidiol oral solution)
Lennox-Gastaut syndrome (LGS) Indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 1 year of age and older. **Dravet syndrome (DS)** Indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 1 year of age and older. **Tuberous sclerosis complex (TSC)** Indicated for the treatment of seizures associated with tuberous sclerosis complex (TSC) in patients 1 year of age and older.

2 . Criteria

Product Name: Epidiolex	
Diagnosis	Lennox-Gastaut syndrome (LGS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPIDIOLEX	CANNABIDIOL SOLN 100 MG/ML	72600017002020	Brand

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

2 - Trial of, contraindication, or intolerance to TWO formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate) [2, A-B]

AND

3 - Patient is 1 year of age or older

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Epidiolex	
Diagnosis	Dravet syndrome (DS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPIDIOLEX	CANNABIDIOL SOLN 100 MG/ML	72600017002020	Brand

Approval Criteria

1 - Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2 - Patient is 1 year of age or older

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Epidiolex	
Diagnosis	Tuberous sclerosis complex
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPIDIOLEX	CANNABIDIOL SOLN 100 MG/ML	72600017002020	Brand

Approval Criteria

1 - Diagnosis of seizures associated with tuberous sclerosis complex (TSC)

AND

2 - Patient is 1 year of age or older

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Epidiolex	
Diagnosis	Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), Tuberous sclerosis complex (TSC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPIDIOLEX	CANNABIDIOL SOLN 100 MG/ML	72600017002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. The effectiveness of Epidiolex for the treatment of seizures associated with LGS was established in two randomized, double-blind, placebo-controlled trials in patients aged 2 to 55 years. In study 2, 225 patients underwent randomization, of whom 76 were assigned to the 20-mg cannabidiol group, 73 to the 10-mg cannabidiol group, and 76 to the placebo group; Patients in each group had previously received a median of 6 antiepileptic drugs (range, 0 to 22), but the drugs had failed to control the seizures; the patients were receiving a median of 3 antiepileptic drugs concomitantly at the time of trial entry. [3]

B. To improve patient care and facilitate clinical research, the International League Against Epilepsy (ILAE) appointed a Task Force to formulate a consensus definition of drug resistant epilepsy. The following definition was formulated: Drug resistant epilepsy may be defined as failure of adequate trials of two tolerated and appropriately chosen and used antiepileptic drug (AED) schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom. [4]

4 . References

1. Epidiolex Prescribing Information. Greenwich Biosciences, Inc. Carlsbad, CA. April 2022.
2. Per clinical consult with neurologist, July 30, 2018.
3. Devinsky O, Patel AD, Cross JH, et al. Effect of cannabidiol on drop seizures in the Lennox-Gastaut syndrome. N Engl J Med. 2018 May 17;378(20):1888-1897.
4. Kwan P, Arzimanoglou A, Berg AT, et al. Definition of drug resistant epilepsy: consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. Epilepsia. 2010 Jun;51(6):1069-77.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160854
Guideline Name	Ergot Alkaloids
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: D.H.E. 45 (dihydroergotamine mesylate) injection
Migraine Indicated for the acute treatment of migraine headaches with or without aura. **Cluster Headache** Indicated for the acute treatment of cluster headache episodes.
Drug Name: Migranal (dihydroergotamine mesylate) nasal spray
Migraine Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.
Drug Name: Cafergot (ergotamine tartrate and caffeine) tablet, Ergomar (ergotamine tartrate) sublingual tablet, Migergot (ergotamine tartrate and caffeine) suppository
Headache Indicated as therapy to abort or prevent vascular headache, e.g., migraine, migraine variants, or so-called “histaminic cephalalgia”.

Drug Name: Trudhesa (dihydroergotamine mesylate) nasal spray
Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: - Not indicated for the preventive treatment of migraine. - Not indicated for the management of hemiplegic or basilar migraine.

2 . Criteria

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, or Trudhesa nasal spray	
Diagnosis	Migraines
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Generic
MIGRANAL	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Brand
D.H.E. 45	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Brand
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Generic
MIGERGOT	ERGOTAMINE W/ CAFFEINE SUPPOS 2-100 MG	67991002105220	Brand
ERGOTAMINE TARTRATE/CAFFEINE	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Generic
CAFERGOT	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Brand
ERGOMAR	ERGOTAMINE TARTRATE SL TAB 2 MG	67000020100705	Brand
TRUDHESA	DIHYDROERGOTAMINE MESYLATE HFA NASAL AEROSOL 0.725 MG/ACT	67000030113420	Brand

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [A]

AND

4 - One of the following: [3]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [B, 4]

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication
- Generic lisinopril unless there is a contraindication or intolerance to this medication

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, or Trudhesa nasal spray	
Diagnosis	Migraines
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Generic
MIGRANAL	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Brand
D.H.E. 45	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Brand
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Generic
MIGERGOT	ERGOTAMINE W/ CAFFEINE SUPPOS 2-100 MG	67991002105220	Brand
ERGOTAMINE TARTRATE/CAFFEINE	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Generic
CAFERGOT	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Brand
ERGOMAR	ERGOTAMINE TARTRATE SL TAB 2 MG	67000020100705	Brand
TRUDHESA	DIHYDROERGOTAMINE MESYLATE HFA NASAL AEROSOL 0.725 MG/ACT	67000030113420	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, or Migergot suppository	
Diagnosis	Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
D.H.E. 45	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Brand
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Generic

MIGERGOT	ERGOTAMINE W/ CAFFEINE SUPPOS 2-100 MG	67991002105220	Brand
ERGOTAMINE TARTRATE/CAFFEINE	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Generic
CAFERGOT	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Brand
ERGOMAR	ERGOTAMINE TARTRATE SL TAB 2 MG	67000020100705	Brand

Approval Criteria

1 - Diagnosis of cluster headache

AND

2 - Patient is 18 years of age or older [A]

AND

3 - Trial and failure, contraindication, or intolerance to sumatriptan injection [5]

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, or Migergot suppository	
Diagnosis	Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
D.H.E. 45	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Brand
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Generic
MIGERGOT	ERGOTAMINE W/ CAFFEINE SUPPOS 2-100 MG	67991002105220	Brand
ERGOTAMINE TARTRATE/CAFFEINE	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Generic

CAFERGOT	ERGOTAMINE W/ CAFFEINE TAB 1-100 MG	67991002100310	Brand
ERGOMAR	ERGOTAMINE TARTRATE SL TAB 2 MG	67000020100705	Brand

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

3 . Endnotes

A. The safety and effectiveness in pediatric patients has not been established. [1, 2]
B. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan. [3, 4]

4 . References

1. D.H.E. 45 Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. April 2022.
2. Migranal Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2022.
3. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.
4. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26.
5. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. Headache. 2016 Jul;56(7):1093-106.
6. Cafergot Prescribing Information. Sandoz Inc. Princeton, NJ. May 2018
7. Ergomar Prescribing Information. TerSera Therapeutics LLC. Deerfield, IL. February 2020.
8. Migergot Prescribing Information. Cosette Pharmaceuticals, Inc.. South Plainfield, NJ. June 2020.
9. Trudhesa Prescribing Information. Impel Pharmaceuticals Inc. Seattle, WA. August 2023.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160855
Guideline Name	Erivedge (vismodegib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Erivedge (vismodegib)
Basal cell carcinoma Indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

2 . Criteria

Product Name: Erivedge	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ERIVEDGE	VISMODEGIB CAP 150 MG	21370070000120	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of metastatic basal cell carcinoma

OR

1.2 Both of the following:

1.2.1 Diagnosis of locally advanced basal cell carcinoma

AND

1.2.2 One of the following:

- Disease recurred following surgery
- Patient is not a candidate for both surgery and radiation

Product Name: Erivedge	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ERIVEDGE	VISMODEGIB CAP 150 MG	21370070000120	Brand

Approval Criteria

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

3 . References

1. Erivedge Prescribing Information. Genentech USA Inc. South San Francisco, CA. August 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 4, 2020..

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160856
Guideline Name	Erythropoietic Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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.

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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Verification of iron evaluation for adequate iron stores^ [A, J]

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

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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 - Verification of iron evaluation for adequate iron stores^ [A, J]

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

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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
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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic
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 - 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 1g/dL from pre-treatment level

AND

4 - Verification of iron evaluation for adequate iron stores^ [A, J]

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 - Verification of iron evaluation for adequate iron stores^ [A, J]

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 - 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

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic

Approval Criteria

1 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

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]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EPOGEN	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
EPOGEN	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
EPOGEN	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
EPOGEN	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic
EPOGEN	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 2000 UNIT/ML	82401020002010	Generic
PROCRIT	EPOETIN ALFA INJ 3000 UNIT/ML	82401020002015	Generic
PROCRIT	EPOETIN ALFA INJ 4000 UNIT/ML	82401020002020	Generic
PROCRIT	EPOETIN ALFA INJ 10000 UNIT/ML	82401020002040	Generic

PROCRIT	EPOETIN ALFA INJ 20000 UNIT/ML	82401020002050	Generic
PROCRIT	EPOETIN ALFA INJ 40000 UNIT/ML	82401020002060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 2000 UNIT/ML	82401020042010	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 3000 UNIT/ML	82401020042015	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 4000 UNIT/ML	82401020042020	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 10000 UNIT/ML	82401020042040	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic

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 1g/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 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

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 - 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]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic

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 - Verification of iron evaluation for adequate iron stores ^ [1-3, 8, 33, G]

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

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic

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 - 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 - Verification of iron evaluation for adequate iron stores ^ [1-3, 8, 33, G]

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

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic

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 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

6 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

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	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 - 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 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

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]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic

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 - Verification of iron evaluation for adequate iron stores ^ [4, A, H]

AND

4 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp

• Retacrit or Procrit	
Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic

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]

- Serum erythropoietin level less than or equal to 500 mU/mL
- Diagnosis of transfusion-dependent MDS

AND

3 - Verification of iron evaluation for adequate iron stores ^ [4, A, H]

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

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic

Approval Criteria

1 - Diagnosis of hepatitis C viral (HCV) infection [12, 20]

AND

2 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

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-2b
- interferon alfacon-1
- peginterferon alfa-2b
- peginterferon alfa-2a

AND

5 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic

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 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

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-2b
- interferon alfacon-1
- peginterferon alfa-2b
- peginterferon alfa-2a

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]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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
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 40000 UNIT/ML	82401020042060	Brand
RETACRIT	EPOETIN ALFA-EPBX INJ 20000 UNIT/ML	82401020042050	Generic
MIRCERA	METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 120 MCG/0.3ML	8240104010E530	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 clinical 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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160857
Guideline Name	Evrysdi (risdiplam)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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

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 requesting risdiplam are not necessary in order to not delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy reauthorization assessment.

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EVRYSDI	RISDIPLAM FOR SOLN 0.75 MG/ML	74706560002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy from pretreatment baseline status as demonstrated by the most recent results from one of the following exams:

1.1 One of the following HINE-2 milestones: [2]

- Improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick
- Improvement or maintenance of previous improvement of at least a 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp
- Patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.2 One of the following HFMSE milestones: [8]

- Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.3 One of the following RULM test milestones: [2, 8-9]

- Improvement or maintenance of a previous improvement of at least a 2 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.4 One of the following CHOP INTEND milestones: [2]

- Improvement or maintenance of a previous improvement of at least a 4 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.5 One of the following MFM-32 milestones: [2]

- Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.6 Improvement in the ability to sit without support for at least 5 seconds as assessed by

item 22 of the Gross Motor Scale of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III) [2-3]

AND

2 - Patient continues to not be dependent on invasive ventilation or tracheostomy [2-3, D]

AND

3 - Patient continues to not be dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [3, D]

AND

4 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

AND

5 - Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza) [2-3, 10, F]

AND

6 - One of the following: [2-3, 10, F]

6.1 Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma)

OR

6.2 Both of the following:

- Patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma)

- Documentation of inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)

3 . Endnotes

A. There were two major Phase 2/3 trials that the FDA assessed when determining Evrysdi's clinical efficacy and subsequent approval (SUNFISH and FIREFISH). SUNFISH only enrolled patients with SMA Types 2 and 3 and FIREFISH only enrolled patients with SMA Type 1. [2-3]
B. This is the definition that the clinical trials SUNFISH and FIREFISH used. Also consistent with clinical guidelines. [2-7]
C. FIREFISH required patients to have 2 copies of SMN2, and SUNFISH only enrolled patients with 2-4 copies of SMN2. [2-3]
D. Invasive ventilation or tracheostomy was an exclusion criteria in both the SUNFISH and FIREFISH trials. Use of non-invasive ventilation beyond use for naps and nighttime sleep was only an exclusion criteria in FIREFISH. [2-3]
E. MFM-32 was included in Evrysdi criteria but not Spinraza because Spinraza did not study MFM-32 as an endpoint. Baseline motor score standards was only used as an inclusion criterion for SUNFISH. Revised upper limb module (RULM) entry item A (Brooke score) equal to or greater than 2 AND MFM-32 (Item 9) scores equal to or greater than 1 were required. As this was only for the SUNFISH trial and only applied to some of the motor scores, it was deemed unnecessary to include as a criterion. [2]
F. A recent European ad-hoc consensus statement on SMA stated that there currently is no published evidence that the combination of two disease modifying therapies (e.g., Evrysdi and Zolgensma) is superior to any single treatment alone. Both FIREFISH and SUNFISH excluded patients that were on concomitant or previous treatment with either SMN2-targeting antisense oligonucleotide, or gene therapy (e.g., Spinraza or Zolgensma). JEWELFISH is an ongoing open label phase 2 trial that included patients previously treated with another SMA targeted therapy (e.g., Zolgensma, Spinraza). JEWELFISH is scheduled to be completed in January 2025. [2-3,10-11]

4 . References

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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160858
Guideline Name	Extended Release Tramadol Products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Conzip
Pain Indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate. Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve CONZIP for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. CONZIP is not indicated as an as-needed (prn) analgesic.
Drug Name: Tramadol Extended Release (ER)
Pain Indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate. Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosages or duration, and because of the greater risks of

overdose and death with extended-release opioid formulations, reserve tramadol hydrochloride extended-release tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Tramadol hydrochloride extended-release tablet is not indicated as an as-needed (prn) analgesic.

2 . Criteria

Product Name: ConZip, tramadol ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRAMADOL HCL ER	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 100 MG	65100095107070	Generic
CONZIP	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 100 MG	65100095107070	Generic
TRAMADOL HCL ER	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 200 MG	65100095107080	Generic
CONZIP	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 200 MG	65100095107080	Generic
TRAMADOL HCL ER	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 300 MG	65100095107090	Generic
CONZIP	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 300 MG	65100095107090	Generic
TRAMADOL HCL ER	TRAMADOL HCL CAP ER 24HR BIPHASIC RELEASE 150 MG	65100095107075	Generic
TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR 100 MG	65100095107520	Generic
TRAMADOL HYDROCHLORIDE ER	TRAMADOL HCL TAB ER 24HR 100 MG	65100095107520	Generic
TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR 200 MG	65100095107530	Generic
TRAMADOL HYDROCHLORIDE ER	TRAMADOL HCL TAB ER 24HR 200 MG	65100095107530	Generic
TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR 300 MG	65100095107540	Generic

TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR BIPHASIC RELEASE 100 MG	65100095107560	Generic
TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR BIPHASIC RELEASE 200 MG	65100095107570	Generic
TRAMADOL HCL ER	TRAMADOL HCL TAB ER 24HR BIPHASIC RELEASE 300 MG	65100095107580	Generic

Approval Criteria

1 - Diagnosis of moderate to moderately severe chronic pain

AND

2 - Trial and failure (of a minimum 30 day supply) or intolerance to an immediate release tramadol containing product (e.g., tramadol, tramadol/acetaminophen)

3 . References

1. Conzip prescribing information. Vectical Pharmaceuticals, LLC. Bridgewater, NJ. December 2023.
2. Tramadol Extended Release prescribing information. Lupin Pharmaceuticals, Inc. Baltimore, MD. January 2024.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160859
Guideline Name	Fecal Microbiota Agents - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rebyota (fecal microbiota, live-jslm) suspension
Recurrent Clostridioides difficile infection (CDI) Indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI. Limitations of use: Rebyota is not indicated for treatment of CDI.
Drug Name: Vowst (fecal microbiota spores, live-brpk) capsule
Recurrent Clostridioides difficile infection (CDI) Indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI). Limitations of use: Vowst is not indicated for treatment of CDI.
Drug Name: Zinplava (bezlotoxumab) injection
Recurrent Clostridioides difficile infection (CDI) Indicated to reduce recurrence of Clostridioides difficile infection (CDI) in adults and pediatric patients 1 year of age and older

who are receiving antibacterial drug treatment for CDI and are at high risk for CDI recurrence.
Limitations of use: Zinplava is not indicated for the treatment of CDI.

2 . Criteria

Product Name: Rebyota	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REBYOTA	FECAL MICROBIOTA, LIVE-JSLM RECTAL SUSP 150 ML	52522010301820	Brand

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of one or more recurrent episodes of CDI

AND

4 - Both of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

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

- Gastroenterologist
- Infectious disease specialist

Product Name: Rebyota	
Approval Length	14 Day(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
REBYOTA	FECAL MICROBIOTA, LIVE-JSLM RECTAL SUSP 150 ML	52522010301820	Brand

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of one or more recurrent episodes of CDI

AND

4 - Both of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

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

- Gastroenterologist
- Infectious disease specialist

Product Name: Vowst	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOWST	FECAL MICROBIOTA SPORES, LIVE-BRPK CAPS	52522020100120	Brand

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of two or more recurrent episodes of CDI within 12 months

AND

4 - All of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst [A]

AND

4.3 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

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

- Gastroenterologist
- Infectious disease specialist

AND

6 - Trial and failure, contraindication or intolerance to Rebyota

Product Name: Vowst	
Approval Length	14 Day(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
VOWST	FECAL MICROBIOTA SPORES, LIVE-BRPK CAPS	52522020100120	Brand

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of two or more recurrent episodes of CDI within 12 months

AND

4 - All of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst [A]

AND

4.3 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

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

- Gastroenterologist
- Infectious disease specialist

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to Rebyota

Product Name: Zinplava	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZINPLAVA	BEZLOTOXUMAB IV SOLN 1000 MG/40ML (25 MG/ML)	19503015002020	Brand

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements in less than or equal to 24 hours
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Used for the reduction of the recurrence of CDI

AND

3 - Used in combination with antibacterial drug treatment for CDI [e.g., oral Vancocin (vancomycin), Flagyl (metronidazole), or Dificid (fidaxomicin)]

AND

4 - Patient is 1 year of age or older

AND

5 - Patient has one or more of the following risk factors associated with CDI recurrence: [5-8, B]

- One or more prior episodes of CDI in the previous 6 months
- Immunocompromised
- Chronic dialysis
- Inflammatory bowel disease
- Continued use of non-CDI antimicrobials after diagnosis of CDI and/or after CDI treatment

AND

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

- Gastroenterologist
- Infectious disease specialist

3 . Endnotes

A. Patients are required to take magnesium citrate 24 hours prior to the first dose of Vowst per the prescribing information. There is currently no efficacy data regarding the use of Vowst without magnesium citrate and the thought is that it helps to clear the antibiotics prior to administration of Vowst. [2,3]

B. Risk factors for CDI recurrence: There is no specific guidance in regards to which patients should be considered high risk for CDI recurrence. There are a multitude of risk factors that increase patients' risk for recurrent CDI. Risk factors reported in one or more previously published studies and confirmed by consultant feedback include: one or more prior episodes of CDI in the previous 6 months, immunocompromised state, renal failure, inflammatory bowel disease, and continued use of non-CDI antimicrobials. Although patients greater than or equal to 65 years of age are at greater risk of recurrent CDI than younger patients, per consultant feedback, not all patients over 65 should be treated with Zinplava, only those with the highest risk. [5-11]

4 . References

1. Rebyota Prescribing Information. Ferring Pharmaceuticals, Inc. Parsippany, NJ. November 2022.
2. Vowst Prescribing Information. Aimmune Therapeutics, Inc. Brisbane, CA. April 2023.
3. Per clinical consult with gastroenterologist, May 3, 2023.
4. Zinplava Prescribing Information. Merck Sharp & Dohme LLC. Rahway, NJ. May 2023.

5. Cohen SH, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). Infect Control Hosp Epidemiol. 2010;31(5):431-55.
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. November 2016.
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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160860
Guideline Name	Ferriprox (deferiprone)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ferriprox (deferiprone) Tablets
Iron Overload Indicated for the treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with thalassemia syndromes, sickle cell disease or other anemias. Limitations of Use: Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.
Drug Name: Ferriprox (deferiprone) Oral Solution
Iron Overload Indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with thalassemia syndromes, sickle cell disease or other anemias. Limitations of Use: Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

2 . Criteria

Product Name: Ferriprox oral solution, Generic deferiprone tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FERRIPROX	DEFERIPRONE ORAL SOLN 100 MG/ML	93100028002020	Brand
DEFERIPRONE	DEFERIPRONE TAB 500 MG	93100028000320	Generic
DEFERIPRONE	DEFERIPRONE TAB 1000 MG	93100028000340	Generic

Approval Criteria

1 - Diagnosis of transfusional iron overload due to one of the following: [1]

- Thalassemia syndromes
- Sickle cell disease
- Other transfusion-dependent anemias

AND

2 - One of the following:

2.1 For Ferriprox oral solution, patient is 3 years of age or older

OR

2.2 For generic deferiprone tablet, patient is 8 years of age or older

AND

3 - Trial (of a minimum 30 day supply) and failure (defined by a serum ferritin > 2,500 mcg/L), contraindication or intolerance to one of the following chelation therapy [A]:

- Generic deferoxamine
- Generic deferasirox

AND

4 - Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L

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

Product Name	Generic Name	GPI	Brand/Generic
FERRIPROX	DEFERIPRONE TAB 500 MG	93100028000320	Brand
FERRIPROX	DEFERIPRONE ORAL SOLN 100 MG/ML	93100028002020	Brand
FERRIPROX	DEFERIPRONE TAB 1000 MG	93100028000340	Brand
FERRIPROX TWICE-A-DAY	DEFERIPRONE (TWICE DAILY) TAB 1000 MG	93100028000345	Brand
DEFERIPRONE	DEFERIPRONE TAB 500 MG	93100028000320	Generic
DEFERIPRONE	DEFERIPRONE TAB 1000 MG	93100028000340	Generic

Approval Criteria

1 - Diagnosis of transfusional iron overload due to one of the following: [1]

- Thalassemia syndromes
- Sickle cell disease
- Other transfusion-dependent anemias

AND

2 - Patient is 8 years of age or older

AND

3 - Trial (of a minimum 30 day supply) and failure (defined by a serum ferritin > 2,500 mcg/L), contraindication or intolerance to one of the following chelation therapy [A]:

- Generic deferoxamine
- Generic deferasirox

AND

4 - Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L

AND

5 - Trial and failure, or intolerance to generic deferiprone tablets*

Notes	*Product may require prior authorization

Product Name: Brand Ferriprox tablet, Ferriprox oral solution, Generic deferiprone tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FERRIPROX	DEFERIPRONE TAB 500 MG	93100028000320	Brand
FERRIPROX	DEFERIPRONE ORAL SOLN 100 MG/ML	93100028002020	Brand
FERRIPROX	DEFERIPRONE TAB 1000 MG	93100028000340	Brand
FERRIPROX TWICE-A-DAY	DEFERIPRONE (TWICE DAILY) TAB 1000 MG	93100028000345	Brand
DEFERIPRONE	DEFERIPRONE TAB 500 MG	93100028000320	Generic
DEFERIPRONE	DEFERIPRONE TAB 1000 MG	93100028000340	Generic

Approval Criteria

1 - Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline

AND

2 - Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L

AND

3 - For Brand Ferriprox tablets, trial and failure, or intolerance to generic deferiprone tablets

3 . Endnotes

A. Failure to prior chelation therapy is defined as serum ferritin > 2,500 mcg/L. [1]

4 . References

1. Ferriprox tablets prescribing information. Apotex Inc., Toronto, Canada. July 2023.
2. Ferriprox solution prescribing information. Apotex Inc., Toronto, Canada. November 2021.
3. Deferiprone prescribing information. Taro Pharmaceutical Industries Ltd. Haifa Bay, Israel. January 2024.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160861
Guideline Name	Flurazepam
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Flurazepam
Insomnia Indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakening. Since insomnia is often transient and intermittent, short-term use is usually sufficient. Prolonged use of hypnotics is usually not indicated and should only be undertaken concomitantly with appropriate evaluation of the patient.

2 . Criteria

Product Name: Flurazepam	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FLURAZEPAM HCL	FLURAZEPAM HCL CAP 15 MG	60201010100105	Generic
FLURAZEPAM HCL	FLURAZEPAM HCL CAP 30 MG	60201010100110	Generic

Approval Criteria

1 - Diagnosis of insomnia

AND

2 - Trial and failure, contraindication, or intolerance to two of the following benzodiazepines: [A]

- Estazolam
- Halcion (triazolam)
- Restoril (temazepam)

3 . Endnotes

A. Flurazepam, estazolam, triazolam, and temazepam are only recommended for patients < 65 years old. These drugs were included on the American Geriatrics Society 2019 Beers Criteria update. [2] Flurazepam was removed in the 2023 AGS Beers Criteria update due to low utilization but is still considered potentially inappropriate in alignment with the 2019 AGS Beers Criteria. [3]

4 . References

1. Flurazepam Prescribing Information. Chartwell RX, LLC. Congers, NY. December 2023.
2. The 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694.
3. American Geriatrics Society 2023 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2023;1-30.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160862
Guideline Name	Galafold (migalastat)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Galafold (migalastat)
Fabry Disease Indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. This indication is approved based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2 . Criteria

Product Name: Galafold	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GALAFOLD	MIGALASTAT HCL CAP 123 MG (BASE EQUIVALENT)	30903650100120	Brand

Approval Criteria

1 - Diagnosis of Fabry Disease

AND

2 - One of the following: [3, 4]

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing
- Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

3 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data [A]

AND

4 - Will not be used in combination with other drugs used for Fabry disease [B]

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

Product Name	Generic Name	GPI	Brand/Generic
GALAFOLD	MIGALASTAT HCL CAP 123 MG (BASE EQUIVALENT)	30903650100120	Brand

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by one of the following: [3, 4]

- Reduction in plasma or urinary sediment lyso-GL-3, GL-3 compared to baseline
- Reduction in number of GL-3 inclusions per kidney interstitial capillary (KIC) in renal biopsy samples compared to baseline
- Improvement and/or stabilization in symptoms (e.g., renal function, neuropathic pain)

AND

2 - Will not be used in combination with other drugs used for Fabry disease [B]

3 . Endnotes

A. In an in vitro assay (HEK-293 assay), Human Embryonic Kidney (HEK-293) cell lines were transfected with specific GLA variants (mutations) which produced mutant alpha-Gal A proteins. A GLA variant was categorized as amenable if the resultant mutant alpha-Gal A activity (measured in the cell lysates) met two criteria: 1) it showed a relative increase of at least 20% compared to the pre-treatment alpha-Gal A activity, and 2) it showed an absolute increase of at least 3% of the wild-type (normal) alpha-Gal A activity. Whether a certain amenable GLA variant in a patient with Fabry disease is disease-causing or not should be determined by the prescribing physician (in consultation with a clinical genetics professional, if needed) prior to treatment initiation. [1]
B. The safety and effectiveness of concomitant use of Galafold and Fabrazyme (agalsidase beta) has not been established. [2]

4 . References

1. Galafold prescribing information. Amicus Therapeutics U.S., Inc. Cranbury, NJ. June 2023.
2. Per clinical consultation with geneticist. October 11, 2018.

3. Ortiz A, Germain DP, Desnick RJ, et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab. 2018;123(4):416-427. doi:10.1016/j.ymgme.2018.02.014.
4. Michaud M, Mauhin W, Belmatoug N, et al. When and How to Diagnose Fabry Disease in Clinical Pratice. Am J Med Sci. 2020;360(6):641-649. doi:10.1016/j.amjms.2020.07.011.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160863
Guideline Name	Gamifant (emapalumab-lzsg)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Gamifant (emapalumab-lzsg)
Primary Hemophagocytic Lymphohistiocytosis (HLH) Indicated for the treatment of adult and pediatric (newborn and older) patients with primary HLH with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

2 . Criteria

Product Name: Gamifant	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 10 MG/2ML	99405035402020	Brand
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 50 MG/10ML	99405035402040	Brand
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 100 MG/20ML	99405035402060	Brand

Approval Criteria

1 - Diagnosis of primary hemophagocytic lymphohistiocytosis (HLH)

AND

2 - One of the following:

2.1 Disease is one of the following:

- Refractory
- Recurrent
- Progressive

OR

2.2 Trial and failure, contraindication, or intolerance to conventional HLH therapy (e.g., etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate)

AND

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

AND

4 - Patient has not received hematopoietic stem cell transplantation (HSCT)

Product Name: Gamifant	
Approval Length	6 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 10 MG/2ML	99405035402020	Brand
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 50 MG/10ML	99405035402040	Brand
GAMIFANT	EMAPALUMAB-LZSG IV SOLN 100 MG/20ML	99405035402060	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers)

AND

2 - Patient has not received HSCT

3 . Endnotes

A. Per clinical consultation, it is appropriate to limit authorization duration to no more than 6 months at a time, given that the ultimate goal in therapy is to receive HSCT and treatment with Gamifant should be viewed as bridge therapy to HSCT. Pivotal trial data duration was also less than 3 months. [2]

4 . References

1. Gamifant Prescribing Information. Sobi Inc. Waltham, MA. June 2020.
2. Per clinical consult with a pediatric hematologist/oncologist, January 18, 2019.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160864
Guideline Name	Gattex (teduglutide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160865
Guideline Name	Gaucher Disease Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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)
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	
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

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]

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.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160866
Guideline Name	Gilenya (fingolimod) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160867
Guideline Name	Gilotrif (afatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 Tumors have 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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160868
Guideline Name	Gleevec (imatinib mesylate) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Gleevec (imatinib mesylate)
Chronic myelogenous/myeloid leukemia (CML) Indicated for the treatment of newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase. Gleevec is also indicated for the treatment of patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy. **Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)** Indicated for the treatment of adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Gleevec is also indicated for the treatment of pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy. **Myelodysplastic/myeloproliferative diseases (MDS/MPD)** Indicated for the treatment of adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.

Aggressive systemic mastocytosis (ASM) Indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown.

Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) Indicated for the treatment of adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRa fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRa fusion kinase negative or unknown.

Dermatofibrosarcoma protuberans (DFSP) Indicated for the treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).

Gastrointestinal stromal tumors (GIST) Indicated for the treatment of patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). Gleevec is also indicated for the adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive GIST.

2 . Criteria

Product Name: Brand Gleevec	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

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

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

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

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

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

Product Name: Brand Gleevec	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

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

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

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

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

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

Product Name: Brand Gleevec	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)

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

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

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

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

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

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

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

Product Name: Brand Gleevec	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

Product Name: Brand Gleevec	
Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of at least one of the following:

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

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec

Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of at least one of the following:

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

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

1 - Diagnosis of at least one of the following:

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

Product Name: Brand Gleevec	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

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

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

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

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

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

Product Name: Brand Gleevec

Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

Product Name: Brand Gleevec, Generic imatinib	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Generic
GLEEVEC	IMATINIB MESYLATE TAB 100 MG (BASE EQUIVALENT)	21531835100320	Brand
IMATINIB MESYLATE	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Generic

GLEEVEC	IMATINIB MESYLATE TAB 400 MG (BASE EQUIVALENT)	21531835100340	Brand

Approval Criteria

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

3 . References

1. Gleevec Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. March 2024

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160869
Guideline Name	Gonadotropin-Releasing Hormone Antagonists (Infertility Agents)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cetrotide (cetrorelix)
Controlled ovarian stimulation Indicated for the inhibition of premature LH surges in women undergoing controlled ovarian stimulation.
Drug Name: Generic ganirelix, Generic Fyremadel
Controlled ovarian stimulation Indicated for the inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation.

2 . Criteria

Product Name: Generic ganirelix*, Generic Fyremadel*

Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GANIRELIX ACETATE	GANIRELIX ACETATE SOLN PREFILLED SYRINGE 250 MCG/0.5ML	3009004010E520	Generic
FYREMADEL	GANIRELIX ACETATE SOLN PREFILLED SYRINGE 250 MCG/0.5ML	3009004010E520	Generic

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (ovarian stimulation)

AND

3 - Will be used in conjunction only with assisted reproductive technology (ART)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Cetrotide*	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CETROTIDE	CETRORELIX ACETATE FOR INJ KIT 0.25 MG	30090025106420	Brand

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (ovarian stimulation)

AND

3 - Will be used in conjunction only with assisted reproductive technology (ART)

AND

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

- Generic Ganirelix
- Generic Fyremadel

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

3 . References

1. Cetrotide Prescribing Information. EMD Serono, Inc. Rockland, MA. June 2024.
2. Ganirelix Acetate Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. May 2024.
3. Fyremadel Prescribing Information. Ferring Pharmaceuticals Inc. Parsippany, NJ. October 2023.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-162304
Guideline Name	Growth Hormones - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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 expected adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand

GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand

GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Submission of medical records (e.g., chart notes) documenting both of the following:

- Patient is female
- Bone age less than 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

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

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

2 - Submission of medical records (e.g., chart notes) documenting height below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zomacton	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
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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
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GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand

GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

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

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claim or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Product Name: Norditropin Flexpro*, Omnitrope*	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.*Approve at NDC list "S OMATROPPA".

Product Name: Norditropin Flexpro*, Omnitrope*	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/1.5ML	3010002000D212	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/1.5ML	3010002000D230	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 15 MG/1.5ML	3010002000D240	Brand
NORDITROPIN FLEXPRO	SOMATROPIN SOLUTION PEN-INJECTOR 30 MG/3ML	3010002000D260	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML	3010002000E210	Brand
OMNITROPE	SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML	3010002000E213	Brand
OMNITROPE	SOMATROPIN FOR INJ 5.8 MG	30100020002123	Brand

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPA".

Product Name: Genotropin [off-label], Humatrope, Nutropin AQ NuSpin [off-label], Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 5 MG	30100020102120	Brand
SAIZEN	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand
ZOMACTON	SOMATROPIN FOR SUBCUTANEOUS INJ 5 MG	30100020002121	Brand
SAIZENPREP RECONSTITUTIONKIT	SOMATROPIN (NON-REFRIGERATED) FOR INJ 8.8 MG	30100020102130	Brand

ZOMACTON	SOMATROPIN FOR INJ 10 MG	30100020002140	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 6 MG (18 UNIT)	3010002000E120	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E130	Brand
HUMATROPE	SOMATROPIN FOR INJ CARTRIDGE 24 MG	3010002000E140	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 5 MG	3010002000E159	Brand
GENOTROPIN	SOMATROPIN FOR SUBCUTANEOUS INJ CARTRIDGE 12 MG (36 UNIT)	3010002000E188	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.2 MG	3010002000E404	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.4 MG	3010002000E407	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.6 MG	3010002000E410	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 0.8 MG	3010002000E413	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1 MG	3010002000E416	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.2 MG	3010002000E419	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.4 MG	3010002000E422	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.6 MG	3010002000E425	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 1.8 MG	3010002000E428	Brand
GENOTROPIN MINIQUICK	SOMATROPIN FOR SUBCUTANEOUS INJ PREFILLED SYR 2 MG	3010002000E431	Brand
NUTROPIN AQ NUSPIN 5	SOMATROPIN SOLUTION PEN-INJECTOR 5 MG/2ML	3010002000D207	Brand
NUTROPIN AQ NUSPIN 10	SOMATROPIN SOLUTION PEN-INJECTOR 10 MG/2ML	3010002000D220	Brand
NUTROPIN AQ NUSPIN 20	SOMATROPIN SOLUTION PEN-INJECTOR 20 MG/2ML	3010002000D250	Brand

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Omnitrope (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal 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 should not be approved

2 . Endnotes

A. Several recent review articles in the literature have suggested that GH stimulation tests should no longer be used to diagnose GHD. [13,14] The authors argue that GH stimulation test may have side effects, lack precision, accuracy, and do not predict response to GH therapy. It has been suggested that newer diagnostic procedures such as serum IGF-1, IGFBP-3 concentrations, genetic testing and neuroimaging could provide an alternative approach to the diagnosis of GHD in childhood.
B. Overall, there are no observable differences in the results obtained among the different preparations as long as the regimen follows currently approved daily injections. Many of the products are available in a variety of injection devices that are meant to make administration more appealing and easier. Currently, there is no evidence that clinical outcome differs among the various injection systems, although there may be patient and parent preferences for some of these devices. [11, 21]
C. Even a 5% weight loss in persons with HIV infection indicates a poor prognosis. [2]
D. Patients with HIV-associated wasting may begin an initial 12-week course of therapy with Serostim, 6 mg/day s.c. The clinician should monitor treatment responses by obtaining serial body weights and BCM measurements by BIA. A positive response to therapy probably should be considered as a 2% increase in body weight and/or BCM. Maintenance therapy may continue on a monthly basis as long as wasting is still evident. Once BCM has normalized, therapy can be stopped, with the patient being observed for an 8-week period. Over these 8 weeks, body weight, BCM, and any appearance of wasting symptoms can be monitored. If wasting reappears, therapy can be restarted. [17]
E. Guidelines for idiopathic short stature recommend against the routine use of GH in every child with height standard deviation score ≤ - 2.25. [23]
F. When GHD is congenital and near complete, the diagnosis is relatively easy to confirm because affected children present with severe growth failure, delayed bone age, and very low serum concentrations of GH, IGF-1, and IGFBP-3 [8]. For patients with all of these clinical characteristics, it is reasonable to make the diagnosis of GHD without performing GH stimulation testing. [29]
G. Measurements of IGF-1 and IGFBP-3 have shown comparable diagnostic performance with growth hormone stimulation tests and are valuable for patient`s convenience and ease of performance and can be useful in the workup of growth hormone deficiency. [30]

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4 . Revision History

Date	Notes
12/20/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-158853
Guideline Name	Halcinonide cream
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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

3 . References

1. Halcinonide Prescribing Information. Glasshouse Pharmaceuticals Limited Canada. Ontario, Canada. October 2020.

Prior Authorization Guideline

Guideline ID	GL-160870
Guideline Name	Harvoni (ledipasvir/sofosbuvir) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Harvoni (ledipasvir/sofosbuvir)
Chronic Hepatitis C (CHC) Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV)]: - Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis; - Genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin; - Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin

2 . Criteria

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir

Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA less than 6 Million IU/mL
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Pre-treatment HCV RNA less than 6 million IU/mL

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following (applies to brand ledipasvir/sofosbuvir only):

7.1 Both of the following:

7.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA less than 6 Million IU/mL
Approval Length	8 Week(s)

Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Submission of medical records documenting pre-treatment HCV RNA less than 6 million IU/mL

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA greater than or equal to 6 Million IU/mL
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Pre-treatment HCV RNA greater than or equal to 6 million IU/mL

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following (applies to brand ledipasvir/sofosbuvir only):

7.1 Both of the following:

7.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA greater than or equal to 6 Million IU/mL
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Submission of medical records documenting pre-treatment HCV RNA greater than or equal to 6 million IU/mL

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Treatment-Naive or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced (No Decompensated Cirrhosis)
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6

AND

2 - One of the following:

- Patient is treatment-naive
- Patient has prior failure to peginterferon alfa plus ribavirin treatment
- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Both of the following:

6.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Treatment-Naive or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced (No Decompensated Cirrhosis)
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6

AND

2 - One of the following:

- Patient is treatment-naive
- Patient has prior failure to peginterferon alfa plus ribavirin treatment

- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Post-Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient is a liver transplant recipient

AND

3 - One of the following:

3.1 Patient is without cirrhosis or has compensated cirrhosis (Child-Pugh Class A)

OR

3.2 Both of the following:

- Patient has decompensated cirrhosis (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Both of the following:

6.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Post-Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient is a liver transplant recipient

AND

3 - One of the following:

3.1 Patient is without cirrhosis or has compensated cirrhosis (Child-Pugh Class A)

OR

3.2 Both of the following:

- Patient has decompensated cirrhosis (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis - Ribavirin Eligible
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - Used in combination with ribavirin

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis - Ribavirin Eligible
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - Used in combination with ribavirin

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

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

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis; Ribavirin Ineligible OR Prior Sovaldi or NS5A-Based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG	12359902400310	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG	12359902403006	Brand
HARVONI	LEDIPASVIR-SOFOSBUVIR PELLET PACK 45-200 MG	12359902403010	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - One of the following:

3.1 Patient is ribavirin ineligible

OR

3.2 Both of the following:

- Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy
- Used in combination with ribavirin

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis; Ribavirin Ineligible OR Prior Sovaldi or NS5A-Based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
LEDIPASVIR/SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG	12359902400320	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - One of the following:

3.1 Patient is ribavirin ineligible

OR

3.2 Both of the following:

- Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy
- Used in combination with ribavirin

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

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

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

1. Harvoni Prescribing Information. Gilead Sciences, Inc. Foster City, CA. March 2020.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-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.

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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-158708
Guideline Name	Hereditary Angioedema Agents - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Berinert (C1 esterase inhibitor [Human])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute abdominal, facial, or laryngeal attacks of HAE in adult and adolescent patients. The safety and efficacy of Berinert for prophylactic therapy have not been established.
Drug Name: Cinryze (C1 esterase inhibitor [Human])
Prophylaxis of Hereditary Angioedema (HAE) Indicated for routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients (6 years old and above) with HAE. **Off Label Uses: Acute treatment of Hereditary Angioedema (HAE)** Following treatment with nanofiltered C1 inhibitor concentrate (Cinryze) for an acute attack, the median time to response was 30 minutes in 82 patients with HAE. [3]
Drug Name: Firazyr (icatibant)

Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of HAE in adults 18 years of age and older.
Drug Name: Haegarda (C1 esterase inhibitor [Human])
Prophylaxis of Hereditary Angioedema (HAE) Indicated for routine prophylaxis to prevent HAE attacks in patients 6 years of age and older.
Drug Name: Kalbitor (ecallantide)
Acute treatment of Hereditary Angioedema (HAE) Indicated for treatment of acute attacks of HAE in patients 12 years of age and older.
Drug Name: Orladeyo (berotralstat)
Prophylaxis of Hereditary Angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older. Limitations of Use: The safety and effectiveness of ORLADEYO for the treatment of acute HAE attacks have not been established. ORLADEYO should not be used for treatment of acute HAE attacks. Additional doses or doses of ORLADEYO higher than 150 mg once daily are not recommended due to the potential for QT prolongation.
Drug Name: Ruconest (C1 esterase inhibitor [Recombinant])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks in adult and adolescent patients with HAE. Limitation of Use: Effectiveness was not established in HAE patients with laryngeal attacks.
Drug Name: Takhzyro (lanadelumab-flyo)
Prophylaxis of Hereditary Angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older.
Drug Name: Sajazir (icatibant)
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

2 . Criteria

Product Name: Cinryze, Haegarda, Orladeyo, Takhzyro	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CINRYZE	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500 UNIT	85802022002120	Brand
HAEGARDA	C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 2000 UNIT	85802022002130	Brand
HAEGARDA	C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 3000 UNIT	85802022002140	Brand
TAKHZYRO	LANADELUMAB-FLYO INJ 300 MG/2ML (150 MG/ML)	85842040202020	Brand
ORLADEYO	BEROTRALSTAT HCL CAP 110 MG	85840010200120	Brand
ORLADEYO	BEROTRALSTAT HCL CAP 150 MG	85840010200130	Brand
TAKHZYRO	LANADELUMAB-FLYO SOLN PREF SYRINGE 300 MG/2ML (150 MG/ML)	8584204020E520	Brand
TAKHZYRO	LANADELUMAB-FLYO SOLN PREF SYRINGE 150 MG/ML	8584204020E510	Brand

Approval Criteria

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

AND

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

2.1 Diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 Normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For prophylaxis against HAE attacks [3]

AND

4 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

AND

5 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze and Haegarda only)
- Patient is 12 years of age or older (applies to Orladeyo only)

- Patient is 2 years of age or older (applies to Takhzyro only)

AND

6 - One of the following:

6.1 Trial and failure, contraindication or intolerance to one of the following: (applies to Cinryze only)

- Orladeyo
- Haegarda
- Takhzyro

OR

6.2 For continuation of prior therapy (applies to Cinryze only)

AND

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

- Immunologist
- Allergist

Product Name: Cinryze, Haegarda, Orladeyo, Takhzyro	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CINRYZE	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500 UNIT	85802022002120	Brand
HAEGARDA	C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 2000 UNIT	85802022002130	Brand
HAEGARDA	C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 3000 UNIT	85802022002140	Brand

TAKHZYRO	LANADELUMAB-FLYO INJ 300 MG/2ML (150 MG/ML)	85842040202020	Brand
ORLADEYO	BEROTRALSTAT HCL CAP 110 MG	85840010200120	Brand
ORLADEYO	BEROTRALSTAT HCL CAP 150 MG	85840010200130	Brand
TAKHZYRO	LANADELUMAB-FLYO SOLN PREF SYRINGE 300 MG/2ML (150 MG/ML)	8584204020E520	Brand
TAKHZYRO	LANADELUMAB-FLYO SOLN PREF SYRINGE 150 MG/ML	8584204020E510	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in the number or rate of HAE attacks while on therapy)

AND

2 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

Product Name: Cinryze [off-label], Brand Firazyr, Generic icatibant, Sajazir, Ruconest, or Kalbitor	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CINRYZE	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500 UNIT	85802022002120	Brand
RUCONEST	C1 ESTERASE INHIBITOR (RECOMBINANT) FOR IV INJ 2100 UNIT	85802022102130	Brand
FIRAZYR	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Brand
ICATIBANT ACETATE	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Generic
SAJAZIR	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Generic

SAJAZIR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
FIRAZYR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Brand
ICATIBANT ACETATE	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
KALBITOR	ECALLANTIDE INJ 10 MG/ML	85840030002020	Brand

Approval Criteria

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

AND

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

2.1 Diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 Normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze only)
- Patient is 12 years of age or older (applies to Kalbitor only) [D]
- Patient is 13 years of age or older (applies to Ruconest only) [5]
- Patient is 18 years of age or older (applies to Brand Firazyr, generic icatibant, and Sajazir only)

AND

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

- Immunologist
- Allergist

AND

7 - Trial and failure or intolerance to generic icatibant (applies to brand Firazyr only):

Product Name: Cinryze [off-label], Brand Firazyr, Generic icatibant, Sajazir, Ruconest, or Kalbitor	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CINRYZE	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500 UNIT	85802022002120	Brand
RUCONEST	C1 ESTERASE INHIBITOR (RECOMBINANT) FOR IV INJ 2100 UNIT	85802022102130	Brand
FIRAZYR	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Brand
ICATIBANT ACETATE	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Generic
SAJAZIR	ICATIBANT ACETATE INJ 30 MG/3ML (BASE EQUIVALENT)	85820040102020	Generic
SAJAZIR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
FIRAZYR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Brand
ICATIBANT ACETATE	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
KALBITOR	ECALLANTIDE INJ 10 MG/ML	85840030002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Not used in combination with other approved treatments for acute HAE attacks

Product Name: Berinert	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BERINERT	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ KIT 500 UNIT	85802022006420	Brand

Approval Criteria

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

AND

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

2.1 Diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 Normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to Ruconest

OR

5.2 One of the following [5]:

- Patient is 12 years of age or younger
- Documentation that patient has history of laryngeal attacks

AND

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

- Immunologist
- Allergist

Product Name: Berinert	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BERINERT	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ KIT 500 UNIT	85802022006420	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Not used in combination with other approved treatments for acute HAE attacks

Product Name: Cinryze	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
CINRYZE	C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500 UNIT	85802022002120	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A]:

2.1 Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:

2.2.1 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 Normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For prophylaxis against HAE attacks [3]

AND

4 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

AND

5 - Patient is 6 years of age or older

AND

6 - One of the following:

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

- Orladeyo
- Haegarda
- Takhzyro

OR

6.2 Both of the following:

6.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

6.2.2 Patient demonstrates positive clinical response to therapy

AND

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

- Immunologist
- Allergist

Product Name: Brand Firazyr, Sajazir	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SAJAZIR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
FIRAZYR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A]:

2.1 Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:

2.2.1 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 Normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation

- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - Patient is 18 years of age or older

AND

6 - Both of the following:

6.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic icatibant

AND

6.2 Submission of medical records confirming generic icatibant has not been effective AND justification/rationale provided explaining how Brand Firazyr or Sajazir is expected to provide benefit when generic icatibant has not been shown to be effective despite having the same active ingredient

AND

7 - One of the following:

7.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication or intolerance to all of the following:

7.1.1 Berinert

AND

7.1.2 Kalbitor

AND

7.1.3 One of the following:

7.1.3.1 Ruconest

OR

7.1.3.2 Documentation that patient has history of laryngeal attacks

OR

7.2 Both of the following:

7.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

7.2.2 Patient demonstrates positive clinical response to therapy

AND

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

- Immunologist
- Allergist

3 . Endnotes

A. HAE is a rare genetic disorder that can be broadly divided into two fundamental types: 1) HAE-C1INH (HAE Type 1 or Type 2), which presents with a deficiency of C1-INH; 2) HAE-n1-C1INH (previously referred to as HAE Type 3), a rare variant which presents with normal C1-INH levels. This condition is inherited in an autosomal dominant manner characterized by recurrent episodes of angioedema, without urticaria or pruritus, which most often affect the skin or mucosal tissues of the upper respiratory and gastrointestinal tracts. Diagnosis of Type 1 or Type 2 HAE requires laboratory testing to confirm low or abnormal levels of C1-inhibitor. HAE-n1-C1INH (previously referred to as HAE Type 3) presents a diagnostic challenge given the current lack of a validated biochemical test to confirm diagnosis. Per HAE guidelines, when a diagnosis of HAE-n1-CINH is suspected based on normal C1-INH levels, diagnosis should be confirmed by a known mutation associated with the disease or a positive family history of recurrent angioedema with a lack of efficacy to high-dose antihistamine therapy [10, 14].

B. Includes immunologist and allergist specialties to ensure the requirement for proper diagnosing and assessing the severity of the symptoms. In the pivotal Cinryze trial, criteria for participation of long term prophylaxis included patients 9 years and older with documented HAE (based on: a low C4 level plus low C1 inhibitor antigenic level/or low C1 inhibitor functional level OR a known HAE causing mutation) AND a history of at least two HAE attack per month. [1, 8] Berinert is approved for the treatment of acute attacks in patients who are 13 years and older. In the pivotal Berinert trial patients had laboratory-confirmed C1-inhibitor deficiency (type I or II HAE). [9]

C. Following treatment with nanofiltered C1 inhibitor concentrate (Cinryze) for an acute attack, the median time to response was 30 minutes in 82 patients with hereditary angioedema (median number of attacks per patient, 3; range, 1 to 57 attacks) in an open-label extension trial (median follow-up of 11 months). Additionally, 93% of attacks responded within 4 hr after C1 inhibitor concentrate treatment. [3]

D. Kalbitor carries a black box warning that states the following: "Anaphylaxis has been reported after administration of Kalbitor. Because of the risk of anaphylaxis, Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema (HAE). Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely. Do not administer Kalbitor to patients with known clinical hypersensitivity to Kalbitor." In 255 HAE patients treated with intravenous or subcutaneous Kalbitor in clinical studies, 10 patients (3.9%) experienced anaphylaxis. For the subgroup of 187 patients treated with subcutaneous Kalbitor, 5 patients (2.7%) experienced anaphylaxis. Symptoms associated with these reactions have included chest discomfort, flushing, pharyngeal edema, pruritus, rhinorrhea, sneezing, nasal congestion, throat irritation, urticaria, wheezing, and hypotension. These reactions occurred within the first hour after dosing. Other adverse reactions indicative of hypersensitivity reactions included the following: pruritus (5.1%), rash (3.1%), and urticaria (2.0%). Patients should be observed for an appropriate period of time after administration of Kalbitor, taking into account the time to onset of anaphylaxis seen in clinical trials. In the Kalbitor HAE program, patients developed antibodies to ecallantide. Rates of seroconversion increased with exposure to ecallantide over time. Overall, 7.4% of patients seroconverted to anti-ecallantide

antibodies. Neutralizing antibodies to ecallantide were determined in vitro to be present in 4.7% of patients. Anti-ecallantide and anti-Po pastoris IgE antibodies were also detected. While the long-term effects of antibodies to Kalbitor are not known, patients who seroconvert may be at a higher risk of a hypersensitivity reaction. The manufacturer developed a Risk Evaluation and Mitigation Strategy (REMS) program consisting of a Medication Guide and Communication Plan to notify healthcare professionals of the risk of anaphylaxis and the need to distinguish signs and symptoms of anaphylaxis and HAE attack as they may overlap. The presence of the black box warning necessitating administration by a healthcare professional; development of antibodies to ecallantide that may predispose patients to higher risks of hypersensitivity reactions; and the requirement for a REMS program offer compelling evidence to warrant the continued inclusion of an age criterion. [7]

E. When HAE is suspected based on the clinical presentation, appropriate testing includes measurement of the serum C4 level, C1INH antigenic level, and C1INH functional level. Low C4 plus low C1INH antigenic or functional levels are consistent with a diagnosis of HAE-C1INH [14, 15].

4 . References

1. Cinryze Prescribing Information. Shire ViroPharma, Inc. Lexington, MA. February 2023.
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15. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema—The 2021 revision and update. European Journal of Allergy and Clinical Immunology. 10 January 2022. Available at: https://onlinelibrary.wiley.com/doi/10.1111/all.15214. Accessed June 26, 2024.

16. Zuraw B, Bork K, et. al. Hereditary angioedema with normal C1 inhibitor - UpToDate web site. Available at: http:www.uptodate.com/. Accessed June 24, 2024.

Prior Authorization Guideline

Guideline ID	GL-160871
Guideline Name	Hetlioz, Hetlioz LQ (tasimelteon) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Hetlioz (tasimelteon) capsule
Non-24-Hour Sleep-Wake Disorder (Non-24) Indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adults. **Smith-Magenis Syndrome (SMS)** Indicated for the treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older.
Drug Name: Hetlioz LQ (tasimelteon) suspension
Smith-Magenis Syndrome (SMS) Indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in pediatric patients 3 to 15 years of age.

2 . Criteria

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand
TASIMELTEON	TASIMELTEON CAPSULE 20 MG	60250070000130	Generic

Approval Criteria

1 - Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome) [2, 5-6, A]

AND

2 - Patient is totally blind (has no light perception) [2-8, B]

AND

3 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)

AND

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

- Specialist in sleep disorders
- Neurologist

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand
TASIMELTEON	TASIMELTEON CAPSULE 20 MG	60250070000130	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand
TASIMELTEON	TASIMELTEON CAPSULE 20 MG	60250070000130	Generic

Approval Criteria

1 - Diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 16 years of age or older

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)

AND

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

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ LQ	TASIMELTEON ORAL SUSP 4 MG/ML	60250070001820	Brand

Approval Criteria

1 - Diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 3 through 15 years of age

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

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

- Specialist in sleep disorders
- Neurologist

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule, Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand
HETLIOZ LQ	TASIMELTEON ORAL SUSP 4 MG/ML	60250070001820	Brand
TASIMELTEON	TASIMELTEON CAPSULE 20 MG	60250070000130	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

Product Name: Hetlioz capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)

Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome) [2, 5-6, A]

AND

2 - Patient is totally blind (has no light perception) [2-8, B]

AND

3 - Submission of medical records (e.g., chart notes) confirming all of the following (Applies to Brand only):

- Patient has experienced intolerance (e.g., allergy to excipient) with generic tasimelteon
- Generic tasimelteon has not been effective
- Justification or rationale explaining how Brand Hetlioz capsule is expected to provide benefit when generic tasimelteon has not been shown to be effective despite having the same active ingredient

AND

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

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz capsule

Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ	TASIMELTEON CAPSULE 20 MG	60250070000130	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 16 years of age or older

AND

3 - Submission of medical records (e.g., chart notes) confirming patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Submission of medical records (e.g., chart notes) confirming all of the following (Applies to Brand only):

- Patient has experienced intolerance (e.g., allergy to excipient) with generic tasimelteon
- Generic tasimelteon has not been effective
- Justification or rationale explaining how Brand Hetlioz capsule is expected to provide benefit when generic tasimelteon has not been shown to be effective despite having the same active ingredient

AND

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

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
HETLIOZ LQ	TASIMELTEON ORAL SUSP 4 MG/ML	60250070001820	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 3 through 15 years of age

AND

3 - Submission of medical records (e.g., chart notes) confirming patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

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

- Specialist in sleep disorders

- Neurologist

3 . Endnotes

A. The International Classification of Sleep Disorders (an official publication of the American Academy of Sleep Medicine) defines non-24-hour sleep-wake disorder as a circadian rhythm sleep disorder characterized by complaints of insomnia or excessive sleepiness related to abnormal synchronization between the 24-hour light-dark cycle and the endogenous circadian rhythms of sleep and wake propensity, for a duration of 3 months. [2] Patients with non-24 experience a chronic steady pattern comprising 1- to 2-hour daily delays in sleep onset and wake times. As incremental phase delays in sleep occur, the complaint will consist of difficulty initiating sleep at night coupled with oversleeping into the daytime hours or inability to remain awake in the daytime. Therefore, over long periods of time, patients alternate between being symptomatic and asymptomatic, depending on the degree of synchrony between their internal biologic rhythm and the 24-hour world. [2] The condition is very rare in normally sighted people, but quite common in the totally blind who have no access to the entraining effects of the light-dark cycle. [3] Of the estimated 1.3 million legally blind individuals in the United States, approximately 130,000 have no light perception. Epidemiologic studies have found that as many as 70% of this totally blind sub-population suffer from non-24. [4] Non-24 is considered a chronic condition and markedly decreases the quality of life for patients. To varying extents, individuals with non-24 are unable to function in scheduled social activities or hold conventional jobs. [2, 4]

B. Hetlioz was approved on the basis of two pivotal, randomized, double-masked, placebo-controlled, multicenter, parallel-group studies in totally blind patients with non-24-hour sleep-wake disorder. [1, 7] The Safety and Efficacy of Tasimelteon (SET) Trial [1,7] was conducted in 84 totally blind patients with non-24, aged 21-84 years. Subjects received either Hetlioz 20 mg or placebo, one hour prior to bedtime, at the same time every night for up to 6 months. The Randomized-withdrawal study of the Efficacy and Safety of Tasimelteon to treat non-24 (RESET) Trial [1,8] was conducted in 20 entrained totally blind patients with non-24, aged 28-70 years. Subjects were treated for approximately 12 weeks with Hetlioz 20 mg one hour prior to bedtime, at the same time every night. Patients in whom the calculated time of peak melatonin level (melatonin acrophase) occurred at approximately the same time of day (in contrast to the expected daily delay) during the run-in phase were randomized to receive placebo or continue treatment with Hetlioz 20 mg for 8 weeks.

C. Given the wide range of available dosing regimens for melatonin, the variability in response time to treatment with tasimelteon and melatonin, and the need for consistent monitoring and evaluation of patients' sleep-related symptoms, tasimelteon must be prescribed by or in consultation with a specialist in sleep disorders. [3]

4 . References

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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160872
Guideline Name	High Cost, Low Value Non-Formulary Program
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name: A Non-Preferred Non-Formulary or Excluded Medication* (Brand Absorica, Absorica LD, Brand Aczone, Brand Adapalene 0.1% pads, Anusol-HC suppository, Arazlo, Atopaderm, Azesco, Bensal HP, Cabtreo, generic chlorzoxazone, Coxanto, Brand Oxaprozin, Brand Diclofenac Epolamine, Brand Doryx, Brand Doryx MPC, generic doxepin cream, Epiceram, generic fenoprofen calcium, Flector, Fluovix, Folic-K, Genicin Vita-S, Brand Inderal XL, Innopran XL, Kamdoy, Kelarx, Licart, Brand Lidocaine-tetracaine cream, Brand Naprosyn, generic naproxen-esomeprazole, Brand Oracea, Ortho DF, Brand Pennsaid, Pliaglis, Pokonza, Pregenna, Prodigen, Promethazine VC syrup, Promethazine/codeine syrup, Brand Prudoxin, Rayos, Relafen DS, Sajazir, Sitavig, Sprix, Tivorbex, Tolsura, Brand Vimovo, Winlevi, Xerese, Xhance, Yosprala, Zipsor, Brand Zonalon, Zorvolex, ZT Lido, Brand Zyclara, Zyflo)	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ABSORICA	ISOTRETINOIN CAP 10 MG	90050013000110	Brand
ABSORICA	ISOTRETINOIN CAP 20 MG	90050013000120	Brand
ABSORICA	ISOTRETINOIN CAP 25 MG	90050013000125	Brand
ABSORICA	ISOTRETINOIN CAP 30 MG	90050013000130	Brand
ABSORICA	ISOTRETINOIN CAP 35 MG	90050013000135	Brand
ABSORICA	ISOTRETINOIN CAP 40 MG	90050013000140	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 8 MG	90050013100110	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 16 MG	90050013100115	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 24 MG	90050013100125	Brand
ABSORICA LD	ISOTRETINOIN MICRONIZED CAP 32 MG	90050013100135	Brand
SITAVIG	ACYCLOVIR BUCCAL TAB 50 MG	12405010000365	Brand
VIMOVO	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 375-20 MG	66109902440620	Brand
NAPROXEN/ESOMEPRAZOLE MAGNESIUM	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 375-20 MG	66109902440620	Generic
VIMOVO	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 500-20 MG	66109902440640	Brand
NAPROXEN/ESOMEPRAZOLE MAGNESIUM	NAPROXEN-ESOMEPRAZOLE MAGNESIUM TAB DR 500-20 MG	66109902440640	Generic
XERESE	ACYCLOVIR-HYDROCORTISONE CREAM 5-1%	90359902153720	Brand
ZIPSOR	DICLOFENAC POTASSIUM CAP 25 MG	66100007100120	Brand
ZYFLO	ZILEUTON TAB 600 MG	44504085000330	Brand
SPRIX	KETOROLAC TROMETHAMINE NASAL SPRAY 15.75 MG/SPRAY	66100037102090	Generic
RELAFEN DS	NABUMETONE TAB 1000 MG	66100055000340	Brand
ZORVOLEX	DICLOFENAC CAP 18 MG	66100007000120	Brand
ZORVOLEX	DICLOFENAC CAP 35 MG	66100007000130	Generic
TOLSURA	ITRACONAZOLE CAP 65 MG	11407035000113	Brand
INNOPRAN XL	PROPRANOLOL HCL SUSTAINED-RELEASE BEADS CAP ER 24HR 80 MG	33100040127020	Brand
INDERAL XL	PROPRANOLOL HCL SUSTAINED-RELEASE BEADS CAP ER 24HR 80 MG	33100040127020	Brand

INNOPRAN XL	PROPRANOLOL HCL SUSTAINED-RELEASE BEADS CAP ER 24HR 120 MG	33100040127030	Brand
INDERAL XL	PROPRANOLOL HCL SUSTAINED-RELEASE BEADS CAP ER 24HR 120 MG	33100040127030	Brand
RAYOS	PREDNISONE TAB DELAYED RELEASE 1 MG	22100045000610	Brand
RAYOS	PREDNISONE TAB DELAYED RELEASE 2 MG	22100045000620	Brand
RAYOS	PREDNISONE TAB DELAYED RELEASE 5 MG	22100045000630	Brand
PENNSAID	DICLOFENAC SODIUM SOLN 2%	90210030302030	Brand
FLECTOR	DICLOFENAC EPOLAMINE PATCH 1.3%	90210030205920	Generic
ZTLIDO	LIDOCAINE PATCH 1.8% (36 MG)	90850060005910	Brand
YOSPRALA	ASPIRIN-OMEPRAZOLE TAB DELAYED RELEASE 81-40 MG	85159902040620	Generic
YOSPRALA	ASPIRIN-OMEPRAZOLE TAB DELAYED RELEASE 325-40 MG	85159902040630	Generic
AZESCO	*PRENATAL VIT W/ FE GLUCONATE-FA TAB 13-1 MG***	78512020000320	Brand
DORYX	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 50 MG	04000020100610	Brand
DORYX	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 80 MG	04000020100624	Brand
DORYX	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 200 MG	04000020100650	Brand
ZYCLARA	IMIQUIMOD CREAM 3.75%	90773040003715	Brand
ATOPADERM	*DERMATOLOGICAL PRODUCTS MISC - CREAM**	90990000003700	Brand
BENSAL HP	SALICYLIC ACID OINT 3%	90750030004210	Brand
CHLORZOXAZONE	CHLORZOXAZONE TAB 250 MG	75100040000305	Generic
CHLORZOXAZONE	CHLORZOXAZONE TAB 375 MG	75100040000307	Generic
CHLORZOXAZONE	CHLORZOXAZONE TAB 500 MG	75100040000310	Generic
CHLORZOXAZONE	CHLORZOXAZONE TAB 750 MG	75100040000320	Generic
EPICERAM	*DERMATOLOGICAL PRODUCTS MISC - EMULSION**	90990000001600	Brand
FENOPROFEN CALCIUM	FENOPROFEN CALCIUM CAP 200 MG	66100010100105	Generic
FENOPROFEN CALCIUM	FENOPROFEN CALCIUM CAP 400 MG	66100010100120	Generic

FENOPROFEN CALCIUM	FENOPROFEN CALCIUM TAB 600 MG	66100010100305	Generic
FLUOVIX	*FLUOCINONIDE CREAM 0.1% & SILICONE TAPE THERAPY PACK***	9055990242B120	Brand
FLUOVIX PLUS	*FLUOCINONIDE CREAM 0.1% & SILICONE TAPE THERAPY PACK***	9055990242B120	Brand
FOLIC-K	*B-COMPLEX W/ E & FOLIC ACID CAP 1 MG***	78133400000120	Brand
GENICIN VITA-S	*B-COMPLEX W/ C & FOLIC ACID TAB 1 MG***	78133000000330	Brand
KAMDOY	*DERMATOLOGICAL PRODUCTS MISC - EMULSION**	90990000001600	Brand
KELARX	*SCAR TREATMENT PRODUCTS - GEL**	90930000004000	Brand
LIDOCAINE AND TETRACAINE CREAM	LIDOCAINE-TETRACAINE CREAM 7-7%	90859902843730	Generic
LIDOCAINE/TETRACAINE	LIDOCAINE-TETRACAINE CREAM 7-7%	90859902843730	Generic
PLIAGLIS	LIDOCAINE-TETRACAINE CREAM 7-7%	90859902843730	Generic
NAPROSYN	NAPROXEN TAB 500 MG	66100060000315	Brand
NAPROSYN	NAPROXEN SUSP 125 MG/5ML	66100060001805	Brand
ORTHO DF	FOLIC ACID-CHOLECALCIFEROL CAP 1 MG-3775 UNIT	82991502400120	Brand
PREGENNA	*PRENAT VIT W/FE BISGLYC CHELATE-FA TAB 20-1MG (1.7MG DFE)**	78512046000315	Brand
PRODIGEN	*PROBIOTIC PRODUCT - CAP**	47300025000100	Brand
TIVORBEX	INDOMETHACIN CAP 20 MG	66100030000104	Generic
ZONALON	DOXEPIN HCL CREAM 5%	90220015103710	Brand
DOXEPIN HYDROCHLORIDE	DOXEPIN HCL CREAM 5%	90220015103710	Generic
PRUDOXIN	DOXEPIN HCL CREAM 5%	90220015103710	Brand
XHANCE	FLUTICASONE PROPIONATE NASAL EXHALER SUSP 93 MCG/ACT	4220003230G720	Brand
DICLOFENAC EPOLAMINE	DICLOFENAC EPOLAMINE PATCH 1.3%	90210030205920	Generic
ZYCLARA PUMP	IMIQUIMOD CREAM 2.5%	90773040003710	Brand
ZYCLARA PUMP	IMIQUIMOD CREAM 3.75%	90773040003715	Brand
FLECTOR	DICLOFENAC EPOLAMINE PATCH 1.3%	90210030205920	Generic

non-preferred			
DORYX MPC	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 60 MG	04000020100615	Brand
DORYX MPC	DOXYCYCLINE HYCLATE TAB DELAYED RELEASE 120 MG	04000020100635	Brand
ADAPALENE	ADAPALENE PADS 0.1%	90050003004310	Brand
POKONZA	POTASSIUM CHLORIDE POWDER PACKET 10 MEQ	79700030003005	Brand
WINLEVI	CLASCOTERONE CREAM 1%	90050011003720	Brand
SAJAZIR	ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF SYR 30 MG/3ML	8582004010E520	Generic
ARAZLO	TAZAROTENE (ACNE) LOTION 0.045%	90050027004120	Brand
COXANTO	OXAPROZIN CAP 300 MG	66100065000120	Generic
OXAPROZIN	OXAPROZIN CAP 300 MG	66100065000120	Generic
CABTREO	ADAPALENE-BENZOYL PEROXIDE-CLINDAMYCIN GEL 0.15-3.1-1.2%	90059903024018	Brand
PROMETHAZINE HYDROCHLORIDE PLAIN	PROMETHAZINE HCL ORAL SOLN 6.25 MG/5ML	41400020102060	Generic
PROMETHAZINE HYDROCHLORIDE	PROMETHAZINE HCL ORAL SOLN 6.25 MG/5ML	41400020102060	Generic
PROMETHAZINE VC	PROMETHAZINE & PHENYLEPHRINE SYRUP 6.25-5 MG/5ML	43993002701210	Generic
LICART	DICLOFENAC EPOLAMINE PATCH 24HR 1.3%	90210030208520	Brand
ORACEA	DOXYCYCLINE (ROSACEA) CAP DELAYED RELEASE 40 MG	90060025006520	Brand
ACZONE	DAPSONE GEL 5%	90051015004020	Brand
ACZONE	DAPSONE GEL 7.5%	90051015004030	Brand
ANUSOL-HC	HYDROCORTISONE ACETATE SUPPOS 25 MG	89100010105230	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming request is for an FDA-approved indication

AND

2 - Submission of medical records (e.g., chart notes) (document drug, duration, dose and date of use) confirming history of use of ALL available formulary alternative(s) and over-the-counter (OTC) equivalents*^ (if request is for a combination product, member must have documentation indicating concurrent use of separate agents)

AND

3 - Both of the following:

3.1 Documentation provided stating the formulary alternative(s) and over-the-counter (OTC) equivalents*^ has/have not been effective

AND

3.2 Justification/rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternative product(s) and over-the-counter (OTC) equivalents*^ has/have not been shown to be effective despite having the same active ingredient and/or same mechanism of action

Notes	*See table in background section for a list of the Non-Formulary or Ex cluded Medications and their preferred formulary alternatives. Please double check plan formulary for coverage. For off-label use, do not re view against the off-label administration guideline. Deny per guideline criteria. ^OTC equivalents refers to any covered or non-covered OTC equivalent product.

2 . Background

Benefit/Coverage/Program Information
Non-Formulary or Excluded Medications and their *^Formulary Alternatives and OTC equivalents

Non-Formulary or Excluded Medication	***^Formulary Alternatives and OTC equivalents**

Brand Absorica, Absorica LD	Amnesteem Claravis Isotretinoin Myorisan Zenatane
Brand Aczone	Amzeeq Cleocin-T Clindacin Clindamycin Klaron Sodium sulfacetamide lotion
Adapalene 0.1% Pads, Arazlo	Aklief Generic adapalene (cream or gel) Generic tretinoin containing products Generic clindamycin containing products Erythromycin/benzoyl peroxide Neuac Tazarotene cream Twyneo
Anusol-HC suppository	Analpram-HC cream Hydrocortisone acetate/pramoxine Proctofoam HC Anusol-HC cream Hydrocortisone Procto-med HC Proctosol HC Proctozone-HC
Atopaderm	Desonide

	Hydrocortisone Aquaphor Eucerin Lubriderm
Azesco	PrePLUS prenatal vitamin CVS prenatal multivitamin Thorne Basic Prenatal Vitamin Aminatal Plus Active OB Atabex OB Tab 29-1mg
Bensal HP	Podofilox Ciclopirox Gold Bond Ultimate Psoriasis Cerave SA moisturizing cream for rough & bumpy skin Q+A Salicylic Acid Smoothing Lotion
Cabtreo	Adapalene Cleocin Clindamycin phosphate/benzoyl peroxide Onexton Clindamycin phosphate/tretinoin Clinoin Erythromycin/benzoyl peroxide Neuac
Coxanto, Brand Oxaprozin	Celecoxib Daypro Diclofenac (oral) Naprosyn

	Naproxen Flurbiprofen Ketoprofen Meloxicam Nabumetone Piroxicam Sulindac
Generic chlorzoxazone	Methocarbamol Cyclobenzaprine tablet Metaxalone Orphenadrine ER Tizanidine
Generic doxepin 5% cream, Brand Prudoxin, Brand Zonalon	Betamethasone dipropionate cream Tacrolimus 0.1% ointment Generic hydrocortisone 1% cream
Brand Doryx, Brand Doryx MPC	Generic doxycycline delayed release Generic doxycycline monohydrate Brand Vibramycin
Epiceram	Aquaphor Eucerin Lubriderm
Generic fenoprofen calcium, Brand Naprosyn	Celecoxib Ibuprofen (tablet/suspension) Diclofenac Etodolac Meloxicam
Flector, Brand Diclofenac epolamine, Licart	Generic topical diclofenac gel

	Celecoxib Ibuprofen (oral) Diclofenac (oral) Etodolac Meloxicam
Fluovix, Fluvovix Plus	Generic fluocinonide cream 0.1%, Generic clobetasol propionate 0.05% cream Generic Halobetasol Propionate 0.05% Cream
Genicin Vita-S	Generic B-Complex with C and Folic Acid Nature's Bounty Super B-complex with Folic Acid Plus Vitamin C Tablets DISCSunmark Vitamin B Complex with Vitamin C Tablets Thorne Ferrasorb
Inderal XL/Innopran XL	Propranolol extended release Nadolol Pindolol Timolol maleate tablets
Kamdoy	Aspercreme Pain Relief Cream with Lidocaine Equate Max Strength Lidocaine Pain Relieving Cream Blue-Emu Lidocaine Pain Relief Cream OTC Lidocaine Cream
Kelarx	Scaraway HF Physician Formulated Silicone Scar Gel Kelo-Cote Scar Gel
Brand Lidocaine-tetracaine cream, Pliaglis	Lidocaine-prilocaine cream Lidocaine cream

	Lidtopic Max Glydo
Brand Oracea	Azelaic acid Doxycycline Finacea Ivermectin Metrocream Metrolotion Metronidazole cream Minocycline Soolantra Zilixi
Ortho DF	Vitamin D3 (OTC) Folic Acid Beeline Vitality Tablets NatureMade Vitamin D/ Folic Acid
Pennsaid	Diclofenac sodium solution 1.5% Diclofenac sodium solution 2% Celecoxib Etodolac Ketoprofen Naproxen Meloxicam Nabumetone Sulindac
Pokonza	Klor-Con Potassium chloride Potassium chloride (CR, ER)

Pregenna	Atabex OB Tab 29-1mg PrePLUS prenatal vitamin CVS prenatal multivitamin Thorne Basic Prenatal Vitamin Aminatal Plus Active OB Vinate II
Prodigen	Alflorex Bio-Kult Visbiome Optibac Probiotics Every Day
Promethazine VC/codeine syrup; promethazine VC syrup	Brompheniramine / dextromethorphan / pseudoephedrine syrup Guaifenesin / pseudoephedrine syrup Guaifenesin / phenylephrine syrup
Relafen DS, Zipsor, Zorvolex	Diclofenac Etodolac Ketoprofen Naproxen Meloxicam Nabumetone Piroxicam Sulindac
Rayos	Medrol Methylprednisolone Pediapred Prednisolone Prednisone

Sajazir	Berinert Ruconest Icatibant acetate
Sitavig	Acyclovir 5% cream Penciclovir 1% cream Acyclovir oral Valacyclovir oral
Sprix	Brand Ketorolac nasal spray Generic ketorolac oral tablets Celecoxib Diclofenac Naprosyn Etodolac Ibuprofen Ketoprofen Sulindac Piroxicam Nabumetone
Tivorbex	Celecoxib Ibuprofen Indomethacin Colcrys Diclofenac Etodolac Meloxicam
Tolsura	Itraconazole 100 mg capsules Sporanox Ketoconazole

<table>
<tr><td rowspan="10">Brand Vimovo, generic naproxen/esomeprazole</td><td>NSAID</td><td>ANTI-ULCER AGENT</td></tr>
<tr><td>Diclofenac</td><td>Esomeprazole</td></tr>
<tr><td>Indomethacin</td><td>Lansoprazole</td></tr>
<tr><td>Ketoprofen</td><td>Omeprazole</td></tr>
<tr><td>Naproxen</td><td>Rabeprazole</td></tr>
<tr><td>Meloxicam</td><td>Pantoprazole</td></tr>
<tr><td>Nabumetone</td><td></td></tr>
<tr><td>Piroxicam</td><td></td></tr>
<tr><td>Sulindac</td><td></td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>Winlevi</td><td colspan="2">Generic adapalene (cream, gel, lotion)
Generic tretinoin containing products
Generic tazarotene cream
Generic single-agent clindamycin product
Generic Dapsone gel</td></tr>
<tr><td>Xerese</td><td colspan="2">Acyclovir 5% Cream
Acyclovir (oral)
Famciclovir (oral)
Hydrocortisone 1% Cream
Penciclovir cream
Valacyclovir (oral)</td></tr>
<tr><td>Xhance</td><td colspan="2">Generic mometasone nasal spray
Generic fluticasone nasal spray
OTC budesonide nasal spray
Omnaris nasal spray
Qnasl nasal spray
OTC triamcinolone nasal spray</td></tr>
</table>

	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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160873
Guideline Name	Ibrance (palbociclib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ibrance (palbociclib)
Breast Cancer Indicated for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with: (1) an aromatase inhibitor as initial endocrine based therapy, or (2) fulvestrant in patients with disease progression following endocrine therapy.

2 . Criteria

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

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IBRANCE	PALBOCICLIB CAP 75 MG	21531060000120	Brand
IBRANCE	PALBOCICLIB CAP 100 MG	21531060000130	Brand
IBRANCE	PALBOCICLIB CAP 125 MG	21531060000140	Brand
IBRANCE	PALBOCICLIB TAB 75 MG	21531060000320	Brand
IBRANCE	PALBOCICLIB TAB 100 MG	21531060000330	Brand
IBRANCE	PALBOCICLIB TAB 125 MG	21531060000340	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kisqali (ribociclib)
- Verzenio (abemaciclib)

OR

2.2 For continuation of prior therapy

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

Product Name	Generic Name	GPI	Brand/Generic
IBRANCE	PALBOCICLIB CAP 75 MG	21531060000120	Brand

IBRANCE	PALBOCICLIB CAP 100 MG	21531060000130	Brand
IBRANCE	PALBOCICLIB CAP 125 MG	21531060000140	Brand
IBRANCE	PALBOCICLIB TAB 75 MG	21531060000320	Brand
IBRANCE	PALBOCICLIB TAB 100 MG	21531060000330	Brand
IBRANCE	PALBOCICLIB TAB 125 MG	21531060000340	Brand

Approval Criteria

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

3 . References

1. Ibrance Prescribing Information. Pfizer Inc. New York, NY. December 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. v.2.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf Accessed April 15, 2022.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160874
Guideline Name	IBS - Diarrhea
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Lotronex (alosetron hydrochloride)
Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women Indicated only for women with severe diarrhea-predominant IBS who have: • chronic IBS symptoms (generally lasting 6 months or longer) • had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and • not responded adequately to conventional therapy. Diarrhea-predominant IBS is severe if it includes diarrhea and one or more of the following: • frequent and severe abdominal pain/discomfort • frequent bowel urgency or fecal incontinence • disability or restriction of daily activities due to IBS. Because of infrequent but serious gastrointestinal adverse reactions associated with Lotronex, the indication is restricted to those patients for whom the benefit-to-risk balance is most favorable. Clinical studies have not been performed to adequately confirm the benefits of Lotronex in men.
Drug Name: Viberzi (eluxadoline)
Irritable bowel syndrome with diarrhea (IBS-D) Indicated in adults for the treatment of IBS-D.

2 . Criteria

Product Name: Brand Lotronex, Generic alosetron	
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LOTRONEX	ALOSETRON HCL TAB 0.5 MG (BASE EQUIV)	52554015100310	Brand
LOTRONEX	ALOSETRON HCL TAB 1 MG (BASE EQUIV)	52554015100320	Brand
ALOSETRON HYDROCHLORIDE	ALOSETRON HCL TAB 0.5 MG (BASE EQUIV)	52554015100310	Generic
ALOSETRON HYDROCHLORIDE	ALOSETRON HCL TAB 1 MG (BASE EQUIV)	52554015100320	Generic

Approval Criteria

1 - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)

AND

2 - Symptoms for at least 6 months [A]

AND

3 - Patient is female

AND

4 - Patient is 18 years of age or older

AND

5 - Trial and failure, contraindication, or intolerance to both of the following:

- antispasmodic agent [eg, Bentyl (dicyclomine)] [2, 6, B]
- antidiarrheal agent [eg, loperamide] [2, 3, 6]

Product Name: Brand Lotronex, Generic alosetron	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LOTRONEX	ALOSETRON HCL TAB 0.5 MG (BASE EQUIV)	52554015100310	Brand
LOTRONEX	ALOSETRON HCL TAB 1 MG (BASE EQUIV)	52554015100320	Brand
ALOSETRON HYDROCHLORIDE	ALOSETRON HCL TAB 0.5 MG (BASE EQUIV)	52554015100310	Generic
ALOSETRON HYDROCHLORIDE	ALOSETRON HCL TAB 1 MG (BASE EQUIV)	52554015100320	Generic

Approval Criteria

1 - Symptoms of IBS continue to persist

AND

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

- Relief of IBS abdominal pain and discomfort
- Improvement in stool consistency
- Decrease in daily stool frequency
- Moderate or substantial improvement as measured by the Global Improvement Scale [C]

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

Product Name	Generic Name	GPI	Brand/Generic
VIBERZI	ELUXADOLINE TAB 75 MG	52558020000330	Brand
VIBERZI	ELUXADOLINE TAB 100 MG	52558020000340	Brand

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea

AND

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

- antispasmodic agent [eg, Bentyl (dicyclomine)] [2, 6]
- antidiarrheal agent [eg, Lomotil (diphenoxylate and atropine)] [2, 3, 6]

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

Product Name	Generic Name	GPI	Brand/Generic
VIBERZI	ELUXADOLINE TAB 75 MG	52558020000330	Brand
VIBERZI	ELUXADOLINE TAB 100 MG	52558020000340	Brand

Approval Criteria

1 - Symptoms of IBS continue to persist

AND

2 - Patient demonstrates positive clinical response to therapy as evidenced by both of the following: [D]

- Improvement in the daily worst abdominal pain score
- Reduction in the Bristol Stool Scale

3 . Endnotes

A. Lotronex was removed from the market in late 2000 due to reports of ischemic colitis and severe constipation but has since been re-released with a “black box” warning for use in select cases. [1, 3, 4, 5]
B. Lotronex should be used with caution in debilitated patients, elderly patients, patients with hepatic impairment, and patients taking medications that decrease gastrointestinal motility. [1]
C. The Global Improvement Scale (GIS) assesses multiple symptoms of Irritable Bowel Syndrome (IBS) using a 7-point Likert scale which ranges from symptoms substantially worse to substantially improved. GIS responders were defined as having moderate or substantial improvement in IBS symptoms. [1]
D. The primary endpoint in Studies 1 and 2 to assess the efficacy of Viberzi was defined by both the simultaneous improvement in the daily worse abdominal pain score by ≥30% as compared to the baseline weekly average AND a reduction in the BSS to <5 on at least 50% of the days within a 12-week time interval. [7]

4 . References

1. Lotronex Prescribing Information. Sebela Pharmaceuticals Inc. Roswell, Georgia, CA. July 2016.
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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160875
Guideline Name	Iclusig (ponatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

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-160876
Guideline Name	Imbruvica (ibrutinib) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Imbruvica (ibrutinib)
Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) with 17p deletion** Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic leukemia (SLL) with 17p deletion **Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma** Indicated for the treatment of adult patients with Waldenström’s macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma [2] **Chronic graft versus host disease (cGVHD)** Indicated for the treatment of adult and pediatric patients age 1 year and older with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

2 . Criteria

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- chronic lymphocytic leukemia
- small lymphocytic lymphoma

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand

IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

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

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- chronic lymphocytic leukemia
- small lymphocytic lymphoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name: Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension

Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- chronic lymphocytic leukemia
- small lymphocytic lymphoma

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

Product Name: Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand

IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

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

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of Waldenstrom's Macroglobulinemia

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

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

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of Waldenstrom's Macroglobulinemia

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name: Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

1 - Diagnosis of Waldenstrom's Macroglobulinemia

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

Product Name: Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

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

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of chronic graft versus host disease (cGVHD)

AND

2 - Patient is 1 year of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate)

AND

4 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

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

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB TAB 140 MG	21532133000320	Brand
IMBRUVICA	IBRUTINIB TAB 280 MG	21532133000330	Brand

Approval Criteria

1 - Diagnosis of chronic graft versus host disease (cGVHD)

AND

2 - Patient is 1 year of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Imbruvica 140mg capsule

Product Name: Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

1 - Diagnosis of chronic graft versus host disease (cGVHD)

AND

2 - Patient is 1 year of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate)

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

Product Name: Imbruvica capsules, Imbruvica 420mg tablet, Imbruvica 560mg tablet, Imbuvica oral suspension	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
IMBRUVICA	IBRUTINIB CAP 70 MG	21532133000110	Brand
IMBRUVICA	IBRUTINIB CAP 140 MG	21532133000120	Brand
IMBRUVICA	IBRUTINIB TAB 420 MG	21532133000340	Brand
IMBRUVICA	IBRUTINIB TAB 560 MG	21532133000350	Brand
IMBRUVICA	IBRUTINIB ORAL SUSP 70 MG/ML	21532133001820	Brand

Approval Criteria

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

Notes	If patient meets criteria above, please approve with GPI List: IMBRUV ICPA

3 . References

1. Imbruvica Prescribing Information. Pharmacyclics, Inc. Sunnyvale, CA. August 2022.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160877
Guideline Name	Immune Globulins - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Bivigam (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated for the treatment of adults and pediatric patients 2 years of age and older with primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Flebogamma 5% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated in adults and pediatric patients 2 years of age and older for the treatment of primary immunodeficiency (PI), including the humoral immune defects in common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency, and Wiskott-Aldrich syndrome.
Drug Name: Flebogamma 10% (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated as replacement therapy in primary immunodeficiency (PI) including the humoral immune defects in common variable immunodeficiency, xlinked agammaglobulinemia, severe combined immunodeficiency, and Wiskott-Aldrich syndrome.

Chronic Primary Immune Thrombocytopenia (ITP) Indicated for the treatment of patients 2 years of age and older with chronic primary ITP to raise platelet count.

Drug Name: Gamastan (immune globulin [Human])

Measles (Rubeola) Indicated to prevent or modify measles in a susceptible person exposed fewer than 6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously. Gamastan may be especially indicated for susceptible household contacts of measles patients, particularly contacts under 1 year of age, for whom the risk of complications is highest. Gamastan is also indicated for pregnant women without evidence of immunity. Gamastan and measles vaccine should not be given at the same time. If a child is older than 12 months and has received Gamastan, he should be given measles vaccine about 5 months later when the measles antibody titer will have disappeared. If a susceptible child exposed to measles is immunocompromised, give Gamastan immediately.

Rubella Indicated to modify rubella in exposed women who will not consider a therapeutic abortion. Some studies suggest that the use of Gamastan in exposed, susceptible women can lessen the likelihood of infection and fetal damage; therefore, Gamastan may benefit those women who will not consider a therapeutic abortion. Do not give Gamastan for routine prophylaxis of rubella in early pregnancy to an unexposed woman.

Hepatitis A Indicated for prophylaxis following exposure to hepatitis A. The prophylactic value of Gamastan is greatest when given before or soon after exposure to hepatitis A. Gamastan is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.

Varicella Indicated to modify varicella. Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella Zoster Immune globulin (Human) [VZIG]. If VZIG is unavailable, Gamastan, promptly given, may also modify varicella.

Drug Name: Privigen (immune globulin [Human])

Chronic Immune Thrombocytopenic Purpura (ITP) Indicated for the treatment of patients age 15 years and older with chronic ITP to raise platelet counts.

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment. Limitation of Use: Privigen maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial

treatment period, not all patients require indefinite maintenance therapy with Privigen in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

Drug Name: Gammagard S/D (immune globulin [Human])

Kawasaki Disease Indicated for the prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients.

B-cell Chronic Lymphocytic Leukemia (CLL) Indicated for prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia (CLL).

Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of adult chronic idiopathic thrombocytopenic purpura to increase platelet count and to prevent and/or to control bleeding.

Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency (PI) associated with defects in humoral immunity, in adults and children two years and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Gammaked and Gamunex-C (immune globulin [Human])

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of CIDP in adults to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.

Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of adults and children with idiopathic thrombocytopenic purpura to raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery.

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Immune globulin products (IVIG)

Off Label Uses: Bone Marrow Transplant (BMT) [6, 19-22] Has been used to decrease the incidence of infections and graft versus host disease (GVHD) in patients 20 years of age and older who underwent bone marrow transplantation.

Dermatomyositis [6, 23] In patients with treatment-resistant dermatomyositis, IVIG therapy resulted in improvements in muscle strength and neuromuscular symptoms.

Multifocal Motor Neuropathy (MMN) [6, 24, 25, 26] In placebo-controlled trials, IVIG has been shown to improve muscle strength and reduce disability and conduction block in patients with MMN.

HIV [6, 27, 28] Used to decrease the frequency of serious and minor bacterial infections; the frequency of hospitalization; and to increase the time free of serious bacterial infections in patients with HIV.

Guillain-Barre Syndrome [6, 29] Considered to be equally effective as plasma exchange for the treatment of Guillain-Barre Syndrome.

Lambert-Eaton Myasthenic Syndrome [6, 30] Considered a first-line treatment option to treat the refractory pattern of weakness seen in patients with LEMS.

Myasthenia Gravis [6, 34] A clinical study comparing IVIG with plasma exchange did not show a significant difference between the two treatments in patients with myasthenia gravis exacerbation. Several open studies support beneficial effects of IVIG in treating myasthenia gravis.

Relapsing Remitting Multiple Sclerosis [6, 35, 36] Published studies indicate that IVIG may reduce the frequency of acute exacerbations and provide symptomatic relief in patients with relapsing-remitting forms of multiple sclerosis.

Stiff-Person Syndrome [6, 64, 65] The efficacy of IVIG for the treatment of stiff-person syndrome was demonstrated in a randomized, double-blind, placebo-controlled, crossover trial.

Polymyositis [6, 23] Found to be effective in reversing chronic polymyositis previously unresponsive to immunosuppressive therapy.

Drug Name: Gammagard Liquid (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Multifocal Motor Neuropathy (MMN) Indicated as a maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy (MMN).

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated as a therapy to improve neuromuscular disability and impairment in adult patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). Limitation of Use: Gammagard Liquid has not been studied in immunoglobulin-naive patients with CIDP. Gammagard Liquid maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with Gammagard Liquid in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

Drug Name: Gammaplex (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated for replacement therapy in primary humoral immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Immune Thrombocytopenic Purpura (ITP) Indicated for the treatment of adults with chronic immune thrombocytopenic purpura (ITP) to raise platelet counts.

Drug Name: Octagam 10% (immune globulin [Human])

Chronic Immune Thrombocytopenic Purpura Indicated in chronic immune thrombocytopenic purpura to rapidly raise platelet counts to control or prevent bleeding in adults.

Dermatomyositis Indicated for the treatment of dermatomyositis in adults.

Drug Name: Octagam 5% (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. These include, but are not limited to: congenital agammaglobulinemia, X-linked agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Cytogam (cytomegalovirus immune globulin [Human])

Cytomegalovirus Indicated for the prophylaxis of cytomegalovirus disease associated with transplantation of kidney, lung, liver, pancreas and heart. In transplants of these organs other than kidney from CMV seropositive donors into seronegative recipients, prophylactic CMV-IGIV should be considered in combination with ganciclovir.

Drug Name: Varizig (varicella zoster immune globulin [Human] solution)

Post-exposure prophylaxis of varicella Indicated for post-exposure prophylaxis of varicella in high risk individuals. High risk groups include: immunocompromised children and adults, newborns of mothers with varicella shortly before or after delivery, premature infants, neonates and infants less than one year of age, adults without evidence of immunity, pregnant women. Limitations of Use: There is no convincing evidence that Varizig reduces the incidence of chickenpox infection after exposure to VZV. There is no convincing evidence that established infections with VZV can be modified by Varizig administration. There is no indication for the prophylactic use of Varizig in immunodeficient children or adults when there is a past history of varicella, unless the patient is undergoing bone marrow transplantation.

Drug Name: Hizentra (immune globulin [Human]) for subcutaneous administration

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia,

common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment. Limitations of Use: Hizentra maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Maintenance therapy beyond these periods should be individualized based upon the patient's response and need for continued therapy.

Drug Name: Panzyga (immune globulin intravenous [Human] - ifas)

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Immune Thrombocytopenia (ITP) Indicated for the treatment of adult patients with ITP to raise platelet counts to control or prevent bleeding.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment.

Drug Name: Cuvitru (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Cutaquig (Immune globulin subcutaneous [Human] - hipp)

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Xembify (immune globulin subcutaneous, human - klhw)

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Asceniv (immune globulin intravenous, human - slra)

Primary Immunodeficiency Disorders Indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age). PI includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID).
Drug Name: HyQvia (immune globulin with recombinant human hyaluronidase) for subcutaneous administration
Primary Immunodeficiency Indicated for the treatment of Primary Immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)** Indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults.
Drug Name: Alyglo (immune globulin intravenous, human-stwk)
Primary Immunodeficiency Disorders Indicated for the treatment of primary humoral immunodeficiency (PI) in adults. This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiency (SCID).

2 . Criteria

Product Name: Intravenous or subcutaneous immune globulins (IVIG or SCIG)	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201020	
Immune globulin (SCIG)	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ	191000202020	

Immune globulin (IVIG/SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	
BIVIGAM			
FLEBOGAMMA DIF			
OCTAGAM			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
HIZENTRA			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 1 GM/6ML	19100020572021	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 1.65 GM/10ML	19100020572025	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 2 GM/12ML	19100020572030	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 3.3 GM/20ML	19100020572035	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 4 GM/24ML	19100020572040	Brand
CUTAQUIG	IMMUNE GLOBULIN (HUMAN)-HIPP SUBCUTANEOUS INJ 8 GM/48ML	19100020572055	Brand
CUVITRU			
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 1 GM/5ML	19100020642020	Brand
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 2 GM/10ML	19100020642025	Brand
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 4 GM/20ML	19100020642030	Brand
XEMBIFY	IMMUNE GLOBULIN (HUMAN)-KLHW SUBCUTANEOUS INJ 10 GM/50ML	19100020642040	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand

HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 1 GM/5ML	1910002020E520	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 2 GM/10ML	1910002020E530	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 4 GM/20ML	1910002020E540	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome [1, 3, 5, 6, 40, 44, 48-64, I, J]

AND

2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [56]

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome [1, 3, 5, 6, 40, 44, 48-64, I, J]

AND

2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [56]

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: HyQvia	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
HYQVIA	IMMUN GLOB INJ 2.5 GM/25ML-HYALURON INJ 200 UNT/1.25 ML KIT	19990002356420	Brand
HYQVIA	IMMUN GLOB INJ 5 GM/50ML-HYALURON INJ 400 UNT/2.5 ML KIT	19990002356425	Brand
HYQVIA	IMMUN GLOB INJ 10 GM/100ML-HYALURON INJ 800 UNT/5 ML KIT	19990002356430	Brand
HYQVIA	IMMUN GLOB INJ 20 GM/200ML-HYALURON INJ 1600 UNT/10 ML KIT	19990002356440	Brand
HYQVIA	IMMUN GLOB INJ 30 GM/300ML-HYALURON INJ 2400 UNT/15 ML KIT	19990002356450	Brand

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome

AND

2 - Patient is 2 years of age or older

AND

3 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [56]

3.1 Documented failure to produce antibodies to specific antigens

OR

3.2 History of significant recurrent infections

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			

FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [3, 5, 45, 51-53, 69]

AND

2 - Documented platelet count of less than 50 x 10^9 / L [66]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga

- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [3, 5, 45, 51-53, 69]

AND

2 - Documented platelet count of less than 50 x 10^9 / L [66]

AND

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

- Bivigam

- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand

ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Kawasaki Disease [5]

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand

ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Kawasaki Disease [5]

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 10-14]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201020	Brand

Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 500 mg/dL) [13, 14, 59, B]

OR

2.2 History of bacterial infection(s) associated with B-cell CLL [13, 14, 59, B]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 10-14]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 500 mg/dL) [13, 14, 59, B]

OR

2.2 History of bacterial infection(s) associated with B-cell CLL [13,14, 59, A]

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG), Hizentra, HyQvia	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15, 17, 18, 41, 45, 55, 78, 79, C, H]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN)IV SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
HIZENTRA			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 1 GM/5ML	1910002020E520	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 2 GM/10ML	1910002020E530	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 4 GM/20ML	1910002020E540	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 1 GM/5ML	19100020202050	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 2 GM/10ML	19100020202054	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 4 GM/20ML	19100020202058	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 10 GM/50ML	19100020202065	Brand
HYQVIA	IMMUN GLOB INJ 2.5 GM/25ML-HYALURON INJ 200 UNT/1.25 ML KIT	19990002356420	Brand
HYQVIA	IMMUN GLOB INJ 5 GM/50ML-HYALURON INJ 400 UNT/2.5 ML KIT	19990002356425	Brand
HYQVIA	IMMUN GLOB INJ 10 GM/100ML-HYALURON INJ 800 UNT/5 ML KIT	19990002356430	Brand

HYQVIA	IMMUN GLOB INJ 20 GM/200ML-HYALURON INJ 1600 UNT/10 ML KIT	19990002356440	Brand
HYQVIA	IMMUN GLOB INJ 30 GM/300ML-HYALURON INJ 2400 UNT/15 ML KIT	19990002356450	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [58, C]:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:

1.2.1 Progressive or relapsing motor impairment of more than one limb

OR

1.2.2 Progressive or relapsing sensory impairment of more than one limb

AND

1.3 Electrophysiologic findings when three of the following four criteria are present:

- Partial conduction block of 1 or more motor nerve
- Reduced conduction velocity of 2 or more motor nerves
- Prolonged distal latency of 2 or more motor nerves
- Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG), Hizentra, HyQvia	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15, 17, 18, 41, 45, 55, 78, 79, C, H]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN)IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			

GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
HIZENTRA			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 1 GM/5ML	1910002020E520	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 2 GM/10ML	1910002020E530	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS SOLN PREF SYR 4 GM/20ML	1910002020E540	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 1 GM/5ML	19100020202050	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 2 GM/10ML	19100020202054	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 4 GM/20ML	19100020202058	Brand
HIZENTRA	IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS INJ 10 GM/50ML	19100020202065	Brand
HYQVIA	IMMUN GLOB INJ 2.5 GM/25ML-HYALURON INJ 200 UNT/1.25 ML KIT	19990002356420	Brand
HYQVIA	IMMUN GLOB INJ 5 GM/50ML-HYALURON INJ 400 UNT/2.5 ML KIT	19990002356425	Brand
HYQVIA	IMMUN GLOB INJ 10 GM/100ML-HYALURON INJ 800 UNT/5 ML KIT	19990002356430	Brand
HYQVIA	IMMUN GLOB INJ 20 GM/200ML-HYALURON INJ 1600 UNT/10 ML KIT	19990002356440	Brand
HYQVIA	IMMUN GLOB INJ 30 GM/300ML-HYALURON INJ 2400 UNT/15 ML KIT	19990002356450	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as measured by an objective scale (e.g., Modified Rankin, Medical Research Council [MRC] scale) [58, H, P]

AND

2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect [P]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15, 17, 18, 41, 45, 55, 78, 79, C, H]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [58, C]:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:

1.2.1 Progressive or relapsing motor impairment of more than one limb

OR

1.2.2 Progressive or relapsing sensory impairment of more than one limb

AND

1.3 Electrophysiologic findings when three of the following four criteria are present:

- Partial conduction block of 1 or more motor nerve
- Reduced conduction velocity of 2 or more motor nerves
- Prolonged distal latency of 2 or more motor nerves
- Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Gamastan	
Diagnosis	Hepatitis A
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMASTAN	IMMUNE GLOBULIN (HUMAN) IM INJ	19100020002200	Brand

Approval Criteria

1 - For prophylaxis of Hepatitis A before or soon after exposure [40, 74]

AND

2 - Patient does not have clinical manifestations of hepatitis A [40, 74]

AND

3 - Patient does not have exposure to hepatitis A for more than 2 weeks previously [40, 74]

Product Name: Gamastan	
Diagnosis	Measles (Rubeola)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

GAMASTAN	IMMUNE GLOBULIN (HUMAN) IM INJ	19100020002200	Brand

Approval Criteria

1 - For use in susceptible individuals exposed to measles fewer than 6 days previously [40, 74]

AND

2 - Patient is not receiving measles vaccine at the same time [40, 74]

Product Name: Gamastan	
Diagnosis	Varicella
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMASTAN	IMMUNE GLOBULIN (HUMAN) IM INJ	19100020002200	Brand

Approval Criteria

1 - For passive immunization against varicella [40, 74]

AND

2 - Patient is immunosuppressed [40, 74]

AND

3 - Varicella Zoster Immune Globulin (Human) vaccine is not available

Product Name: Gamastan

Diagnosis	Rubella
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMASTAN	IMMUNE GLOBULIN (HUMAN) IM INJ	19100020002200	Brand

Approval Criteria

1 - For pregnant women who are exposed or susceptible to Rubella [40, 74]

AND

2 - Patient will not consider a therapeutic abortion [40, 74]

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Bone Marrow Transplantation (off-label) [19-22]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			

GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Confirmed allogeneic bone marrow transplant within the last 100 days [19-21, D]

AND

2 - Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL) [19, D]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Bone Marrow Transplantation (off-label) [19-22]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Confirmed allogeneic bone marrow transplant within the last 100 days [19-21, D]

AND

2 - Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL) [19, D]

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga

- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	HIV (off-label) [60, 61, 86]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand

ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of HIV disease [60, 61, K]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 400 mg/dL) [75, L]

OR

2.2 Functional antibody deficiency as demonstrated by one of the following: [60]

- Poor specific antibody titers
- Recurrent bacterial infections

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	HIV (off-label) [60, 61, 86]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of HIV disease [60, 61, K]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 400 mg/dL) [75, L]

OR

2.2 Functional antibody deficiency as demonstrated by one of the following: [60]

- Poor specific antibody titers
- Recurrent bacterial infections

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [25, 26]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			

PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [57, 67, 68, N]:

1.1 Weakness with slowly progressive or stepwise progressive course over at least one month

AND

1.2 Asymmetric involvement of two or more nerves

AND

1.3 Absence of both of the following:

1.3.1 Motor neuron signs

AND

1.3.2 Bulbar signs

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [25, 26]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			

PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale] [57, 68]

AND

2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Diagnosis	Multifocal Motor Neuropathy (off-label) [25, 26]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [57, 67, 68, N]:

1.1 Weakness with slowly progressive or stepwise progressive course over at least one month

AND

1.2 Asymmetric involvement of two or more nerves

AND

1.3 Absence of both of the following:

1.3.1 Motor neuron signs

AND

1.3.2 Bulbar signs

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [35, 36]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			

GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of relapsing remitting multiple sclerosis (RRMS) [6, 35, 36, G]

AND

2 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy [6, 35, 36, G, M, O]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following agents: [36, G, M, O]

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Betaseron (interferon beta-1b)*
- Copaxone/Glatopa (glatiramer acetate)*
- Extavia (interferon beta-1b)*
- Gilenya (Fingolimod)*
- Lemtrada (alemtuzumab)*
- Plegridy (peginterferon beta-1a)*
- Rebif (interferon beta-1a)*

- Tecfidera (dimethyl fumarate)*
- Tysabri (natalizumab)*

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Notes	*This agent may require prior authorization.

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [35, 36]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			

GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - The prescriber maintains and provides chart documentation of the patient's evaluation, including both of the following [6, 35, 36, O]:

1.1 Findings of interval examination including neurological deficits incurred

AND

1.2 Assessment of disability (e.g., Expanded Disability Status Score [EDSS], Functional Systems Score [FSS], Multiple Sclerosis Functional Composite [MSFC], Disease Steps [DS])

AND

2 - Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS) [6, 35, 36]

AND

3 - Documentation of decreased number of relapses since starting immune globulin therapy [6, 35, 36]

AND

4 - Diagnosis continues to be the relapsing-remitting form of MS (RRMS)

AND

5 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

6 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

7 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [35, 36]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of relapsing remitting multiple sclerosis (RRMS)) [6, 35, 36, G]

AND

2 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy [6, 35, 36, G, M, O]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following agents: [36, G, M, O]

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Betaseron (interferon beta-1b)*
- Copaxone/Glatopa (glatiramer acetate)*
- Generic dimethyl fumarate
- Gilenya (Fingolimod)*
- Lemtrada (alemtuzumab)*
- Tysabri (natalizumab)*

AND

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

- Bivigam
- Gammagard

- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Notes	*This agent may require prior authorization.

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Myasthenia Gravis Exacerbation (off-label) [34]
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand

ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis [34, 55, F, R]

AND

2 - Evidence of myasthenic exacerbation, defined by one of the following symptoms in the last month: [34, 55, F, R]

2.1 Difficulty swallowing

OR

2.2 Acute respiratory failure

OR

2.3 Major functional disability responsible for the discontinuation of physical activity

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine), unless contraindicated, will be used for long-term management of myasthenia gravis [34, 55, F, R]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Myasthenia Gravis Exacerbation (off-label) [34]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis [34, 55, F, R]

AND

2 - Evidence of myasthenic exacerbation, defined by one of the following symptoms in the last month: [34, 55, F, R]

2.1 Difficulty swallowing

OR

2.2 Acute respiratory failure

OR

2.3 Major functional disability responsible for the discontinuation of physical activity

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine), unless contraindicated, will be used for long-term management of myasthenia gravis [34, 55, F, R]

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [64, 65]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of stiff-person syndrome [64, 65]

AND

2 - Trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [64, 65]

AND

3 - Trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [64, 65]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [64, 65]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam

- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Stiff Person Syndrome (off-label) [64, 65]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of stiff-person syndrome [64, 65]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [64, 65]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [64, 65]

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 23, 47]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand

BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - One of the following diagnoses [23]:

- Dermatomyositis
- Polymyositis

AND

2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [23, Q]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 23, 47]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			

PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 23, 47]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - One of the following diagnoses [23]:

- Dermatomyositis
- Polymyositis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [23, Q]

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [29, 80, 83]
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Patients with severe disease requiring aid to walk [80, E]

AND

3 - Onset of neuropathic symptoms within the last four weeks [80, E]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [29, 80, 83]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam

- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Guillain-Barre Syndrome (off-label) [29, 80, 83]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Patients with severe disease requiring aid to walk [80, E]

AND

3 - Onset of neuropathic symptoms within the last four weeks [80, E]

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [84]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			

GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS)

AND

2 - History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [62, 63]

AND

3 - Concomitant immunomodulator therapy (eg, azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [62, 63]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam

- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [84]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201021	Brand
Immune globulin (IVIG)	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN	191000201020	Brand
Immune globulin (IVIG, SCIG)	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN	191000203020	Brand
BIVIGAM			
FLEBOGAMMA DIF			
GAMMAGARD LIQUID			
GAMMAGARD S/D			
GAMMAKED			
GAMMAPLEX			
GAMUNEX-C			
OCTAGAM			
PRIVIGEN			
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN	191000206020	Brand

ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [84]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [62, 63]

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [62, 63]

AND

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

- Bivigam
- Gammagard
- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Cytogam	
Diagnosis	Prophylaxis for CMV Infection
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CYTOGAM	CYTOMEGALOVIRUS IMMUNE GLOBULIN (HUMAN) IV INJ	19100005002200	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient requires prophylaxis for CMV infection following kidney transplantation

AND

1.1.2 Patient is CMV- seronegative and organ donor is CMV-seropositive

OR

1.2 All of the following:

1.2.1 Patient requires prophylaxis for CMV infection following liver, heart, lung, or pancreas transplantation

AND

1.2.2 Patient is CMV- seronegative and organ donor is CMV-seropositive

AND

1.2.3 Used in combination with ganciclovir or valganciclovir unless the patient has a hypersensitivity to, is intolerant of, or therapy is deemed inappropriate

Product Name: Varizig	
Diagnosis	Varicella
Approval Length	1 Dose
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VARIZIG	VARICELLA-ZOSTER IMMUNE GLOB (HUMAN) IM INJ 125 UNIT/1.2ML	19100070002015	Brand
VARIZIG	VARICELLA-ZOSTER IMMUNE GLOB (HUMAN) FOR IM INJ 125 UNIT	19100070002122	Brand
VARIZIG			

Approval Criteria

1 - For passive immunization or post exposure-prophylaxis of varicella

AND

2 - Patient is considered a high risk individual (e.g., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old)

AND

3 - Prescribed immune globulin is being used intramuscularly

Product Name: Intravenous immune globulin (IVIG)

Diagnosis	Pediatric Acute-Onset Neuropsychiatric Syndrome/Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANS/PANDAS) (off-label)
Approval Length	6 Month(s) [74]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
GAMMAPLEX	IMMUNE GLOBULIN (HUMAN) IV SOLN 2.5 GM/50ML	19100020102034	Brand
GAMMAPLEX	IMMUNE GLOBULIN (HUMAN) IV SOLN 5 GM/100ML	19100020102038	Brand
GAMMAPLEX	IMMUNE GLOBULIN (HUMAN) IV SOLN 10 GM/200ML	19100020102042	Brand
FLEBOGAMMA DIF	IMMUNE GLOBULIN (HUMAN) IV SOLN 20 GM/400ML	19100020102044	Brand
BIVIGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 5 GM/50ML	19100020102068	Brand
PRIVIGEN	IMMUNE GLOBULIN (HUMAN) IV SOLN 10 GM/100ML	19100020102072	Brand
BIVIGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 10 GM/100ML	19100020102072	Brand
FLEBOGAMMA DIF	IMMUNE GLOBULIN (HUMAN) IV SOLN 10 GM/100ML	19100020102072	Brand
PRIVIGEN	IMMUNE GLOBULIN (HUMAN) IV SOLN 20 GM/200ML	19100020102076	Brand
FLEBOGAMMA DIF	IMMUNE GLOBULIN (HUMAN) IV SOLN 20 GM/200ML	19100020102076	Brand
GAMMAGARD S/D	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN 2.5 GM	19100020102115	Brand
GAMMAGARD S/D	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN 5 GM	19100020102120	Brand
GAMMAGARD S/D IGA LESS THAN 1MCG/ML	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN 5 GM	19100020102120	Brand
GAMMAGARD S/D	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN 10 GM	19100020102130	Brand
GAMMAGARD S/D IGA LESS THAN 1MCG/ML	IMMUNE GLOBULIN (HUMAN) IV FOR SOLN 10 GM	19100020102130	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 1 GM/10ML	19100020302060	Brand
GAMUNEX-C	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 1 GM/10ML	19100020302060	Brand

GAMMAKED	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 1 GM/10ML	19100020302060	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 2.5 GM/25ML	19100020302064	Brand
GAMUNEX-C	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 2.5 GM/25ML	19100020302064	Brand
GAMMAKED	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 2.5 GM/25ML	19100020302064	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 5 GM/50ML	19100020302068	Brand
GAMUNEX-C	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 5 GM/50ML	19100020302068	Brand
GAMMAKED	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 5 GM/50ML	19100020302068	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 10 GM/100ML	19100020302072	Brand
GAMUNEX-C	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 10 GM/100ML	19100020302072	Brand
GAMMAKED	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 10 GM/100ML	19100020302072	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 20 GM/200ML	19100020302076	Brand
GAMUNEX-C	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 20 GM/200ML	19100020302076	Brand
GAMMAKED	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 20 GM/200ML	19100020302076	Brand
GAMMAGARD LIQUID	IMMUNE GLOBULIN (HUMAN) IV OR SUBCUTANEOUS SOLN 30 GM/300ML	19100020302080	Brand
OCTAGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 2 GM/20ML	19100020102063	Brand
OCTAGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 5 GM/50ML	19100020102068	Brand
OCTAGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 10 GM/100ML	19100020102072	Brand
OCTAGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 20 GM/200ML	19100020102076	Brand
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 1 GM/10ML	19100020602020	Brand
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 2.5 GM/25ML	19100020602025	Brand
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 5 GM/50ML	19100020602030	Brand
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 10 GM/100ML	19100020602035	Brand
PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 20 GM/200ML	19100020602040	Brand

PANZYGA	IMMUNE GLOBULIN (HUMAN)-IFAS IV SOLN 30 GM/300ML	19100020602045	Brand
OCTAGAM	IMMUNE GLOBULIN (HUMAN) IV SOLN 30 GM/300ML	19100020102080	Brand
ASCENIV	IMMUNE GLOBULIN (HUMAN)-SLRA IV SOLN 5 GM/50ML	19100020802030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 5 GM/50ML	19100020832030	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 10 GM/100ML	19100020832035	Brand
ALYGLO	IMMUNE GLOBULIN (HUMAN)-STWK IV SOLN 20 GM/200ML	19100020832040	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)
- Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)

AND

2 - Disease is moderate to severe as defined by distressing symptoms that interfere with daily activities that occupy at least 50 percent (%) of waking hours [75]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [76]

- Corticosteroids (e.g., prednisone, dexamethasone, methylprednisolone)
- NSAIDs (e.g., Ibuprofen, naproxen, celecoxib)

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo and Asceniv only):

- Bivigam
- Gammagard

- Gammaplex
- Gamunex-C
- Panzyga
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

3 . Endnotes

A. Guidelines from the British Committee for Standards in Haematology [11] and the National Comprehensive Cancer Network [16] state that IVIG therapy may be beneficial in patients with recurrent infections. Clinical studies show that IVIG reduces the number of bacterial infections, but not viral or fungal infections. [22]
B. Based on inclusion criteria from Molica et al. [14]
C. According to published data, there appears to be no difference in efficacy among IVIG, plasma exchange, and corticosteroids. [15, 16]
D. A controlled trial indicated that treatment with IVIG beyond three months was associated with a delayed recovery of humoral immunity, and the rate of infections after two years of treatment was increased significantly in IVIG recipients. [23] Centers for Disease Control and Prevention, Infectious Disease Society of America, and American Society of Blood and Marrow Transplantation guidelines recommended routine IVIG use to prevent bacterial infections among BMT recipients with unrelated marrow grafts who experience severe hypogammaglobulinemia (e.g., IgG < 400 mg/dl) within the first 100 days after transplant. [19]
E. The American Academy of Neurology recommends that IVIG is for patients with GBS who require aid to walk within 2 weeks from the onset of neuropathic symptoms. [80]
F. The effectiveness of IVIG for moderate-to-severe but stable myasthenia gravis, or for moderate exacerbations of myasthenia gravis have not been demonstrated in adequately controlled trials. [34] IVIG may be as effective as plasma exchange for patients with acute exacerbations of myasthenia gravis. The indications for the use of IVIG are the same as those for plasma exchange: to produce rapid improvement to help the patient through a difficult period of myasthenic weakness. It has the advantages of not requiring special equipment or large-bore vascular access. [42] The usual dose of immune globulin is 400 mg per kilogram per day for five successive days. The improvement rate after immune globulin treatment, calculated from eight published reports, was 73 percent, but this figure is likely to be biased by selective reporting of positive uncontrolled trials. In patients who respond, improvement begins within four to five days. The effect is temporary but may be sustained for weeks to months, allowing intermittent long-term therapy in patients with otherwise refractory disease.
G. Guidelines from the American Academy of Neurology [87] state that interferon Beta or glatirimer are appropriate treatments for patients who have relapsing-remitting multiple sclerosis. The guidelines state that it is only possible that IVIG reduces the attack rate in

RRMS, and that current evidence suggests IVIG is of little benefit with regard to slowing disease progression.

H. Treatment for CIDP includes corticosteroids such as prednisone, which may be prescribed alone or in combination with immunosuppressant drugs. [41] Plasmapheresis and intravenous immunoglobulin (IVIG) therapy are effective. IVIG may be used even as a first-line therapy. Physiotherapy may improve muscle strength, function and mobility, and minimize the shrinkage of muscles and tendons and distortions of the joints.

I. Subcutaneous formulations of immune globulin are available for the treatment of patients with primary immune deficiency. Subcutaneous infusions may be an alternative for patients with adverse effects to intravenous infusions of immune globulin or with poor venous access. Other advantages include decreased cost of administration, independence from scheduled home nursing visits, better maintenance of intravenous immune globulin trough levels, and a serum IgG profile (smaller variation in the peak and trough IgG concentrations compared to intravenous administration) that is similar to that in a normal population. Disadvantages include more frequent infusions and local reactions. [6]

J. There are good data to show that all immune globulins (IVIG/SCIG) are effective for primary immunodeficiency. There are no data for SCIG for indications other than PI. Efficacy is a class effect for all immune globulins products. It is appropriate to combine all IVIG/SCIG products as they are used interchangeably for PI; can combine all IVIG for other indications. Gamastan S/D (IMIG) has unique indications and should be available on the formulary. [85]

K. IVIG has been used in children with symptomatic human immunodeficiency virus (HIV) infection who are immunosuppressed in association with acquired immunodeficiency syndrome (AIDS) or AIDS-related complex (ARC) in an attempt to control or prevent infections and improve immunologic parameters. Results of studies in adults and children with symptomatic HIV infection indicate that IVIG, used in dosages similar to those used for replacement therapy in patients with primary immunodeficiencies, reduces the incidence of recurrent bacterial infections and sepsis, including upper respiratory tract infections. [86]

L. The ACIP, American Academy of Pediatrics (AAP), Centers for Disease Control (CDC), National Institutes of Health (NIH), HIV Medicine Association of the Infectious Diseases Society of America (IDSA), Pediatric Infectious Diseases Society, and other experts state that HIV-infected infants and children who have hypogammaglobulinemia (IgG less than 400 mg/dL) should receive IVIG (400 mg/kg once every 2-4 weeks) to prevent serious bacterial infections. [86]

M. Per expert consultant regarding MS: IVIG is only used in acute, severe MS. IVIG is used for bad relapses of MS with significant neurological dysfunction when a patient is breaking through their regular maintenance medications. It takes about 3 months to see if there is improvement in MS and one cannot say a patient has failed a medication if they have a breakthrough episode of MS within this 3 month period [67].

N. Per expert consultant regarding multifocal motor neuropathy: the European Federation of Neurological Societies (EFNS) guidelines [69] as outlined on page 344 and in the table are fairly reasonable: 1. Weakness with slowly progressive or stepwise progressive course 2. Asymmetric involvement of two or more nerves 3. Absence of upper motor neuron signs and bulbar signs [68].

O. Per expert consultant regarding MS: there are no data to support the initial length of IVIG treatment in MS. I would suggest 3 months and then reevaluate. An appropriate length of time for reauthorization of IVIG is 12 months. Patients who receive IVIG for RRMS should be in acute exacerbation, should have tried steroids, have documentation of inability to tolerate other disease modifying drugs, as well as show progression of

disease. IVIG should be used 2nd or 3rd line if other injectable disease modifying drugs are not tolerated. Guidelines do not support IVIG as first line treatment for MS [68].

P. Per expert consultant regarding CIDP: It is important to reevaluate a patient after initial treatment. Some patients may need changes in dosing intervals due to wearing off of a dose within 2-3 weeks. Treatment can be lifelong for some patient [68].
Q. Per expert consultant regarding dermatomyositis: It is reasonable to ask a patient to try steroids prior to treatment with IVIG. [68]
R. Per expert consultant regarding MG: IVIG should be used in patients with moderate to severe myasthenia gravis with acute exacerbation. Most MDs favor plasma exchange for maintenance therapy in MG patients. Myasthenic exacerbation = myasthenic crisis. [68]

4 . References

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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160878
Guideline Name	Increlex (mecasermin [rDNA origin])
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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

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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160879
Guideline Name	Infliximab – PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Remicade (infliximab), Infliximab, Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Renflexis (Infliximab-abda)
Rheumatoid Arthritis (RA) Indicated in combination with methotrexate, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. **Psoriatic Arthritis (PsA)** Indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. **Plaque Psoriasis (PsO)** Indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. Therapy should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. **Ankylosing Spondylitis (AS)** Indicated for reducing signs and symptoms in patients with

active ankylosing spondylitis.

Crohn's Disease (CD) Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.

Pediatric Crohn's Disease Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis (UC) Indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Off Label Uses: Sarcoidosis Has been used for the treatment of refractory sarcoidosis. [5-7]

Drug Name: Zymfentra (infliximab-dyyb) SC injection

Crohn's Disease (CD) Indicated in adults for maintenance treatment of moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously.

Ulcerative Colitis (UC) Indicated in adults for maintenance treatment of moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously.

2 . Criteria

Product Name: Avsola, Inflectra	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

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

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Used in combination with methotrexate

Product Name: Avsola, Inflectra	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand

AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

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

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

Product Name: Avsola, Inflectra	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [4]:

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

AND

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

- Dermatologist
- Rheumatologist

Product Name: Avsola, Inflectra	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

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

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

Product Name: Avsola, Inflectra	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - One of the following [5]:

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

AND

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

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Avsola, Inflectra	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to infliximab therapy as evidenced by ONE of the following [1, 5]

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

Product Name: Avsola, Inflectra	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

Product Name: Avsola, Inflectra	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 7]:

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

Product Name: Avsola, Inflectra	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - One of the following diagnoses:

- Moderately to severely active Crohn's disease
- Fistulizing Crohn's disease

AND

2 - One of the following [8, 9]:

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

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [8, 9]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

Product Name: Zymfentra	
Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

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

AND

2 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Avsola, Inflectra, Zymfentra	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 8, 9]:

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

Product Name: Zymfentra	
Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

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

AND

2 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Submission of medical records (e.g., chart notes) confirming the provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Avsola, Inflectra	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [10, 11]:

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

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [10, 11]:

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

- Azathioprine
- Corticosteroids (e.g., prednisone)

Product Name: Zymfentra	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Avsola, Inflectra, Zymfentra	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 10, 11]:

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

Product Name: Zymfentra	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZYMFENTRA 2-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 1-PEN	INFLIXIMAB-DYYB SOLN AUTO-INJECTOR KIT 120 MG/ML	5250504020F530	Brand
ZYMFENTRA 2-SYRINGE	INFLIXIMAB-DYYB SOLN PREFILLED SYRINGE KIT 120 MG/ML	5250504020F830	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Submission of medical records (e.g., chart notes) confirming the provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Avsola, Inflectra	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Diagnosis of sarcoidosis

AND

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

- Pulmonologist
- Dermatologist
- Ophthalmologist

AND

3 - Trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone)

AND

4 - Trial and failure, contraindication, or intolerance to one immunosuppressant (e.g., methotrexate, cyclophosphamide, or azathioprine)

Product Name: Avsola, Inflectra	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INFLECTRA	INFLIXIMAB-DYYB FOR IV INJ 100 MG	52505040202120	Brand
AVSOLA	INFLIXIMAB-AXXQ FOR IV INJ 100 MG	52505040132120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to infliximab therapy

Product Name: Remicade, Infliximab, Renflexis	
Approval Length	12 month(s)
Guideline Type	Prior Authorization, Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
REMICADE	INFLIXIMAB FOR IV INJ 100 MG	52505040002120	Brand
RENFLEXIS	INFLIXIMAB-ABDA FOR IV INJ 100 MG	52505040102120	Brand
INFLIXIMAB	INFLIXIMAB FOR IV INJ 100 MG	52505040002120	Brand

Approval Criteria

1 - Patient has one of the following diagnoses:

- Rheumatoid arthritis (RA)
- Psoriatic Arthritis (PsA)
- Plaque Psoriasis (PsO)

- Ankylosing Spondylitis (AS)
- Crohn's Disease (CD) or Fistulizing Crohn's Disease
- Ulcerative Colitis (UC)
- Sarcoidosis (off-label)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of BOTH of the following:

- Avsola
- Inflectra

AND

3 - Submission of medical records documenting why the covered products have not been effective

3 . References

1. Remicade Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 2021.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
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4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
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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.
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12. DRUGDEX System [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed July 7, 2020.
13. Baughman RP, Drent M, Kavuru M, et al. Infliximab therapy in patients with chronic sarcoidosis and pulmonary involvement Am J Respir Crit Care Med. 2006 Oct 1;174(7):795-802.
14. Rossman M, Newman LS, Baughman RP, et al. A double-blinded, randomized, placebo-controlled trial of infliximab in subjects with active pulmonary sarcoidosis. Sarcoidosis Vasc Diffuse Lung Dis. 2006;23(3):201-8.
15. Per clinical consult with dermatologist. June 26, 2019.
16. Avsola Prescribing Information. Amgen Inc. Thousand Oaks, CA. September 2021.
17. Inflectra prescribing information. Hospira. Lake Forest, IL. March 2022.
18. Renflexis Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. December 2023.
19. Infliximab Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 2021.
20. Zymfentra Prescribing Information. Celltrion USA, Inc. Jersey City, NJ. February 2024.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160880
Guideline Name	Inhaled Corticosteroids - ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Alvesco (ciclesonide) Inhalation Aerosol
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older. Important Limitations of Use: Alvesco is NOT indicated for the relief of acute bronchospasm or for children under 12 years of age.
Drug Name: ArmonAir Digihaler (fluticasone propionate) Inhalation Powder
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Limitations of Use: ArmonAir Digihaler is not indicated for the relief of acute bronchospasm.
Drug Name: Asmanex HFA (mometasone furoate) Inhalation Aerosol
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. Important Limitations of Use: Asmanex HFA is NOT indicated for the relief of acute bronchospasm.

Drug Name: Asmanex (mometasone furoate) Inhalation Powder
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older. Limitations of Use: Asmanex Twisthaler is NOT indicated for the relief of acute bronchospasm or in children less than 4 years of age.
Drug Name: Flovent (fluticasone propionate aerosol) HFA
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients aged 4 years and older. Limitations of Use FLOVENT HFA is not indicated for the relief of acute bronchospasm.
Drug Name: Flovent (fluticasone propionate powder) Diskus
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients aged 4 years and older. Important Limitation of Use FLOVENT DISKUS is NOT indicated for the relief of acute bronchospasm.
Drug Name: Pulmicort (budesonide aerosol) Flexhaler
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients six years of age or older. Limitations of Use: PULMICORT FLEXHALER is NOT indicated for the relief of acute bronchospasm.

2 . Criteria

Product Name: Armonair Digihaler*, Asmanex Twisthaler*, Flovent Diskus, Pulmicort Flexhaler, Brand Fluticasone Propionate Diskus	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ASMANEX TWISTHALER 30 METERED DOSES	MOMETASONE FUROATE INHAL POWD 110 MCG/INH (BREATH ACTIVATED)	44400036208010	Brand
ASMANEX TWISTHALER 120 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand
ASMANEX TWISTHALER	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand

60 METERED DOSES			
ASMANEX TWISTHALER 14 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand
ASMANEX TWISTHALER 30 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand
ASMANEX 14 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Brand
ASMANEX TWISTHALER 30 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Generic
ASMANEX TWISTHALER 14 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Generic
ASMANEX TWISTHALER 60 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Generic
ASMANEX TWISTHALER 120 METERED DOSES	MOMETASONE FUROATE INHAL POWD 220 MCG/INH (BREATH ACTIVATED)	44400036208020	Generic
ARMONAIR DIGIHALER	FLUTICASONE PROPIONATE AER POW BA 55 MCG/ACT WITH SENSOR	44400033218020	Brand
ARMONAIR DIGIHALER	FLUTICASONE PROPIONATE AER POW BA 113 MCG/ACT WITH SENSOR	44400033218030	Brand
ARMONAIR DIGIHALER	FLUTICASONE PROPIONATE AER POW BA 232 MCG/ACT WITH SENSOR	44400033218040	Brand
FLOVENT DISKUS	FLUTICASONE PROPIONATE AER POW BA 50 MCG/ACT	44400033208010	Brand
FLOVENT DISKUS	FLUTICASONE PROPIONATE AER POW BA 100 MCG/ACT	44400033208020	Brand
FLOVENT DISKUS	FLUTICASONE PROPIONATE AER POW BA 250 MCG/ACT	44400033208030	Brand
PULMICORT FLEXHALER	BUDESONIDE INHAL AERO POWD 90 MCG/ACT (BREATH ACTIVATED)	44400015008009	Generic
PULMICORT FLEXHALER	BUDESONIDE INHAL AERO POWD 180 MCG/ACT (BREATH ACTIVATED)	44400015008018	Generic
FLUTICASONE PROPIONATE DISKUS	FLUTICASONE PROPIONATE AER POW BA 50 MCG/ACT	44400033208010	Generic

FLUTICASONE PROPIONATE DISKUS	FLUTICASONE PROPIONATE AER POW BA 100 MCG/ACT	44400033208020	Generic
FLUTICASONE PROPIONATE DISKUS	FLUTICASONE PROPIONATE AER POW BA 250 MCG/ACT	44400033208030	Generic

Approval Criteria

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

AND

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

- Arnuity Ellipta
- QVAR Redihaler

Notes	*Product may be excluded depending on the plan.

Product Name: Flovent HFA, Brand Fluticasone Propionate HFA, Alvesco*, Asmanex HFA*	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ALVESCO	CICLESONIDE INHAL AEROSOL 80 MCG/ACT	44400017003420	Brand
ALVESCO	CICLESONIDE INHAL AEROSOL 160 MCG/ACT	44400017003440	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 50 MCG/ACT	44400036203210	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 100 MCG/ACT	44400036203220	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 200 MCG/ACT	44400036203230	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AERO 44 MCG/ACT (50/VALVE)	44400033223220	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AER 110 MCG/ACT (125/VALVE)	44400033223230	Generic

FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AER 220 MCG/ACT (250/VALVE)	44400033223240	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AERO 44 MCG/ACT (50/VALVE)	44400033223220	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AER 110 MCG/ACT (125/VALVE)	44400033223230	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AER 220 MCG/ACT (250/VALVE)	44400033223240	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 50 MCG/ACT	44400036203210	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 100 MCG/ACT	44400036203220	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 200 MCG/ACT	44400036203230	Brand

Approval Criteria

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

AND

2 - One of the following:

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

- Arnuity Ellipta
- QVAR Redihaler

OR

2.2 Submission of medical records (e.g., chart notes) confirming patient requires a metered dose inhaler used with a spacer device due to one of the following:

- Physical dexterity
- Inspiratory flow
- Cognitive status

Notes	*Product may be excluded depending on the plan.

Product Name: Flovent HFA, Brand Fluticasone Propionate HFA, Alvesco, Asmanex HFA	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ALVESCO	CICLESONIDE INHAL AEROSOL 80 MCG/ACT	44400017003420	Brand
ALVESCO	CICLESONIDE INHAL AEROSOL 160 MCG/ACT	44400017003440	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 50 MCG/ACT	44400036203210	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 100 MCG/ACT	44400036203220	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 200 MCG/ACT	44400036203230	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AERO 44 MCG/ACT (50/VALVE)	44400033223220	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AER 110 MCG/ACT (125/VALVE)	44400033223230	Generic
FLOVENT HFA	FLUTICASONE PROPIONATE HFA INHAL AER 220 MCG/ACT (250/VALVE)	44400033223240	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AERO 44 MCG/ACT (50/VALVE)	44400033223220	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AER 110 MCG/ACT (125/VALVE)	44400033223230	Generic
FLUTICASONE PROPIONATE HFA	FLUTICASONE PROPIONATE HFA INHAL AER 220 MCG/ACT (250/VALVE)	44400033223240	Generic
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 50 MCG/ACT	44400036203210	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 100 MCG/ACT	44400036203220	Brand
ASMANEX HFA	MOMETASONE FUROATE INHAL AEROSOL SUSPENSION 200 MCG/ACT	44400036203230	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

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

AND

1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

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

AND

2 - One of the following:

2.1 Submission of medical records (e.g., chart notes) confirming patient requires a metered dose inhaler used with a spacer device due to one of the following: [A, 9]

- Physical dexterity
- Inspiratory flow
- Cognitive status

OR

2.2 Submission of medical records (e.g., chart notes) or paid claims documenting patient has tried and failed, or has contraindication or intolerance to at least 3 formulary alternatives. If only 1 or only 2 alternatives are available, the patient must have failed or had contraindications or intolerance to all available formulary alternatives

3 . Endnotes

A. Dry powder inhalers are not suitable for those unable to use breath activated devices, such as young children or some elderly patients; pressurized metered dose inhalers with spacers remain essential for such patients. [9]

4 . References

1. Alvesco [prescribing information]. Zug 6300, Switzerland: Covis Pharma; February 2023.
2. ArmonAir Digihaler [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.
3. Asmanex [prescribing information]. Jersey City, NJ: Organon LLC; June 2021.
4. Asmanex HFA [prescribing information]. Jersey City, NJ: Organon LLC; March 2023.
5. Flovent HFA Prescribing Information. GlaxoSmithKline. Durham, NC. September 2023.
6. Flovent Diskus Prescribing Information. GlaxoSmithKline. Durham, NC. August 2023.
7. Pulmicort Flexhaler Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington DE. October 2019.
8. Fluticasone Propionate Diskus Prescribing Information. Prasco Laboratories Mason OH. May 2023.
9. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention 2023. Updated July 2023. Available from www.ginaasthma.org

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160881
Guideline Name	Inlyta (axitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Inlyta (axitinib)
Advanced Renal Cell Carcinoma Indicated in combination with avelumab or pembrolizumab, for the first-line treatment of patients with advanced renal cell carcinoma (RCC). It is also indicated as a single agent, for the treatment of advanced RCC after failure of one prior systemic therapy.

2 . Criteria

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

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
INLYTA	AXITINIB TAB 1 MG	21335013000320	Brand
INLYTA	AXITINIB TAB 5 MG	21335013000340	Brand

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following:

2.1 Used as first-line treatment in combination with one of the following for clear cell renal cell carcinoma**: [2]

- avelumab*
- pembrolizumab*

OR

2.2 Used after failure of one prior systemic therapy (e.g., chemotherapy) for clear cell renal cell carcinoma** [2]

OR

2.3 One of the following:

2.3.1 Both of the following: [2]

- Used in the treatment of non-clear cell renal cell carcinoma
- Trial and failure, contraindication or intolerance to generic sunitinib

OR

2.3.2 For continuation of prior therapy	
Notes	*This product may require prior authorization. ***Criterion is part of FDA-approved label

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

Product Name	Generic Name	GPI	Brand/Generic
INLYTA	AXITINIB TAB 1 MG	21335013000320	Brand
INLYTA	AXITINIB TAB 5 MG	21335013000340	Brand

Approval Criteria

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

3 . References

1. Inlyta Prescribing Information. Pfizer Labs. New York, NY. July 2024.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. v.1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed July 30, 2024.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160882
Guideline Name	Inqovi (decitabine and cedazuridine) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Inqovi (decitabine and cedazuridine)
Myelodysplastic Syndromes (MDS) Indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

2 . Criteria

Product Name: Inqovi

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

Product Name	Generic Name	GPI	Brand/Generic
INQOVI	DECITABINE-CEDAZURIDINE TAB 35-100 MG	21990002250320	Brand

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

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

Product Name	Generic Name	GPI	Brand/Generic
INQOVI	DECITABINE-CEDAZURIDINE TAB 35-100 MG	21990002250320	Brand

Approval Criteria

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

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

Product Name	Generic Name	GPI	Brand/Generic
INQOVI	DECITABINE-CEDAZURIDINE TAB 35-100 MG	21990002250320	Brand

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

3 . References

1. Inqovi prescribing information. Taiho Oncology, Inc. Princeton, NY. March 2022.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160883
Guideline Name	Insomnia Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Edluar (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. The clinical trials performed with zolpidem tartrate in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.
Drug Name: Ambien (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.
Drug Name: Ambien CR (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

Drug Name: Quviviq (daridorexant)
Insomnia Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance in adults.
Drug Name: Belsomra (suvorexant)
Insomnia Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Dayvigo (lemborexant)
Insomnia Indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Zolpidem tartrate capsule
Insomnia Indicated for the short-term treatment of transient insomnia characterized by difficulties with sleep initiation in adults younger than 65 years of age.

2 . Criteria

Product Name: Ambien, Ambien CR, Brand Zolpidem capsules, Edluar	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
EDLUAR	ZOLPIDEM TARTRATE SL TAB 5 MG	60204080100720	Brand
EDLUAR	ZOLPIDEM TARTRATE SL TAB 10 MG	60204080100730	Brand
AMBIEN	ZOLPIDEM TARTRATE TAB 5 MG	60204080100310	Brand
AMBIEN	ZOLPIDEM TARTRATE TAB 10 MG	60204080100315	Brand
AMBIEN CR	ZOLPIDEM TARTRATE TAB ER 6.25 MG	60204080100410	Brand
AMBIEN CR	ZOLPIDEM TARTRATE TAB ER 12.5 MG	60204080100420	Brand
ZOLPIDEM TARTRATE	ZOLPIDEM TARTRATE CAP 7.5 MG	60204080100120	Brand

Approval Criteria

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

AND

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

- zolpidem
- zolpidem ER

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

Product Name	Generic Name	GPI	Brand/Generic
QUVIVIQ	DARIDOREXANT HCL TAB 25 MG	60500020100320	Brand
QUVIVIQ	DARIDOREXANT HCL TAB 50 MG	60500020100340	Brand

Approval Criteria

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

AND

2 - ONE of the following:

2.1 If the patient is less than 65 years of age, BOTH of the following:

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

- Belsomra*
- Dayvigo*

AND

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

- eszopiclone
- zaleplon
- zolpidem
- zolpidem ER
- triazolam
- temazepam
- generic ramelteon
- doxepin

OR

2.2 If the patient is 65 years of age and older, trial and failure (of a minimum 30-day supply), contraindication, or intolerance to TWO of the following:

- generic ramelteon
- Belsomra*
- Dayvigo*
- doxepin

Notes	*NOTE: Step Therapy (ST) requirements may apply for brand Belsomra and brand Dayvigo

Product Name: Belsomra, Dayvigo	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
BELSOMRA	SUVOREXANT TAB 5 MG	60500070000305	Brand
BELSOMRA	SUVOREXANT TAB 10 MG	60500070000310	Brand
BELSOMRA	SUVOREXANT TAB 15 MG	60500070000315	Brand
BELSOMRA	SUVOREXANT TAB 20 MG	60500070000320	Brand
DAYVIGO	LEMBOREXANT TAB 5 MG	60500040000320	Brand
DAYVIGO	LEMBOREXANT TAB 10 MG	60500040000340	Brand

Approval Criteria

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

AND

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

- doxepin
- eszopiclone
- temazepam
- zaleplon
- zolpidem
- zolpidem ER

3 . References

1. Edluar Prescribing Information. Meda Pharmaceuticals Inc. Somerset, NJ. August 2022.
2. Ambien Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. February 2022.
3. Ambien CR Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. February 2022.
4. Quviviq Prescribing Information. Idorsia Pharmaceuticals US Inc. Radnor, PA. April 2023.
5. Belsomra Prescribing Information. Merck Sharp & Dohme LLC. Rahway, NJ. February 2023.
6. Dayvigo Prescribing Information. Eisai Inc. Nutley, NJ. May 2023.
7. The 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc 00:1-21, 2019. Available at https://www.uclahealth.org/geriatrics/workfiles/education/clinical-skills/handouts/Education-Updated-Beers-List-2019.pdf. Accessed August 7, 2023.
8. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: An American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(2):307-349. Available at https://jcsm.aasm.org/doi/10.5664/jcsm.6470. Accessed August 7, 2023.
9. UpToDate. Overview of the Treatment of Insomnia in Adults. Available at https://www.uptodate.com/contents/overview-of-the-treatment-of-insomnia-in-adults?search=insomnia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed August 7, 2023.

10. Zolpidem Prescribing Information. Almatica Pharma LLC. Morristown, NJ. May 2023.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160884
Guideline Name	Insulin Delivery Systems
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name: Insulin dosers, cartridges, or pen devices	
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Insulin			
Delivery			
System			
pen			
doser			
cartridge			

Approval Criteria

1 - Will be approved, except when excluded as a plan benefit, based on one of the following criteria:

1.1 The patient has visual impairment (unable to use insulin vial and syringe)

OR

1.2 The patient has physical impairment (unable to use insulin vial and syringe)

2 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160885
Guideline Name	Interstitial Lung Disease (ILD) Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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. October 2022.
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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160886
Guideline Name	Jakafi (ruxolitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Jakafi (ruxolitinib)
Myelofibrosis Indicated for treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults. **Polycythemia Vera** Indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. **Acute Graft Versus Host Disease** Indicated for treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older. **Chronic Graft Versus Host Disease** Indicated for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

2 . Criteria

Product Name: Jakafi	
Diagnosis	Myelofibrosis
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - One of the following diagnoses:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

Product Name: Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	8 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - Diagnosis of polycythemia vera [1]

AND

2 - Trial and failure, contraindication, or intolerance to hydroxyurea [1]

Product Name: Jakafi	
Diagnosis	Myelofibrosis, Polycythemia Vera
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., spleen volume reduction, symptom improvement, hematocrit control)

Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a 2-month authorization should be issued one time for Jakafi gradual therapy discontinuation.

Product Name: Jakafi	
Diagnosis	Acute Graft Versus Host Disease
Approval Length	6 Month(s) [C]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - Diagnosis of acute graft-versus-host disease

AND

2 - Disease is steroid-refractory

AND

3 - Patient is 12 years of age or older

Product Name: Jakafi	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Patient is 12 years of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)

Product Name: Jakafi	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JAKAFI	RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)	21537560200310	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT)	21537560200320	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT)	21537560200325	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT)	21537560200330	Brand
JAKAFI	RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT)	21537560200335	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. Jakafi should be discontinued after 6 months if there is no spleen size reduction or symptom improvement since initiation of therapy. [1]
B. The initial authorization duration of 8 months is based on clinical trials (primary endpoint of hematocrit control and spleen volume reduction was evaluated at 32 weeks). [1]
C. Authorization duration of 6 months is based median time from response to death or need for new therapy for acute GVHD in clinical trials (173 days). Additionally, tapering of Jakafi may be considered after 6 months of treatment in patients with response who have discontinued therapeutic doses of corticosteroids. [1]

4 . References

1. Jakafi Prescribing Information. Incyte Corp. Wilmington, DE. January 2023.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160887
Guideline Name	Kalydeco (ivacaftor)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Kalydeco (ivacaftor)
Cystic fibrosis Indicated for the treatment of cystic fibrosis (CF) in patients age 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

2 . Criteria

Product Name: Kalydeco

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

Product Name	Generic Name	GPI	Brand/Generic
KALYDECO	IVACAFTOR TAB 150 MG	45302030000320	Brand
KALYDECO	IVACAFTOR PACKET 50 MG	45302030003020	Brand
KALYDECO	IVACAFTOR PACKET 75 MG	45302030003030	Brand
KALYDECO	IVACAFTOR PACKET 13.4 MG	45302030003005	Brand
KALYDECO	IVACAFTOR PACKET 25 MG	45302030003010	Brand
KALYDECO	IVACAFTOR PACKET 5.8 MG	45302030003002	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data* as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 1 month of age or older

AND

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

- Specialist affiliated with a CF care center
- Pulmonologist

Notes	*Please consult Background section for table of CFTR gene mutations responsive to Kalydeco.

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

Product Name	Generic Name	GPI	Brand/Generic
KALYDECO	IVACAFTOR TAB 150 MG	45302030000320	Brand
KALYDECO	IVACAFTOR PACKET 50 MG	45302030003020	Brand
KALYDECO	IVACAFTOR PACKET 75 MG	45302030003030	Brand
KALYDECO	IVACAFTOR PACKET 25 MG	45302030003010	Brand
KALYDECO	IVACAFTOR PACKET 13.4 MG	45302030003005	Brand
KALYDECO	IVACAFTOR PACKET 5.8 MG	45302030003002	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response (i.e., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}], decreased number of pulmonary exacerbations) to therapy [A]

3 . Background

Clinical Practice Guidelines

CFTR Gene Mutations that are Responsive to Kalydeco [1]

*Intent of table is to provide a quick reference; PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 1/24/24]

List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to KALYDE				
*711+3A→G **	*F311del*	*I148T*	*R75Q*	*S589N*

*2789+5G→A **	*F311L*	*I175V*	*R117C **	*S737F*
*3272-26A→G **	*F508C*	*I807M*	*R117G*	*S945L **
*3849+10kbC→T **	*F508C;S1251N † **	*I1027T*	*R117H **	*S977F **
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W **	*R170H*	*S1251N **
*A455E **	*G178R **	*L320V*	*R347H **	*S1255P **
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q **	*T1053I*
D110H	*G551D **	*L1480P*	*R553Q*	*V232D*
D192G	*G551S **	*M152V*	*R668C*	*V562I*
*D579G **	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
*D1152H **	*G1069R*	*P67L **	*R1070Q*	*W1282R*
D1270N	*G1244E **	*Q237E*	*R1070W **	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D **	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N **	
*E831X **	*H1375P*	*R74W*	*S549R **	

** Clinical data exist for these mutations.*

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations these exist independent of the presence of mutations on the other allele.

4 . Endnotes

A. The primary efficacy endpoint in both Kalydeco pivotal trials was improvement in lung function as determined by the mean absolute change from baseline in percent predicted pre-dose FEV1 through 24 weeks of treatment. [2]

5 . References

1. Kalydeco Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. August 2023.
2. Ramsey BW, Davies J, McElvaney G, et al. A CFTR potentiator in patients with cystic fibrosis and the G551D mutation. N Engl J Med. 2011;365:1663-1672.

6 . Revision History

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

Prior Authorization Guideline

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

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-160888
Guideline Name	Koselugo (selumetinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Koselugo (selumetinib)
Neurofibromatosis Type 1 Indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN)

2 . Criteria

Product Name: Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	6 Month(s) [A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KOSELUGO	SELUMETINIB SULFATE CAP 10 MG	21533565500110	Brand
KOSELUGO	SELUMETINIB SULFATE CAP 25 MG	21533565500125	Brand

Approval Criteria

1 - Diagnosis of neurofibromatosis type 1

AND

2 - Patient has plexiform neurofibromas that are both of the following:

- Inoperable [B]
- Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment)

AND

3 - One of the following:

3.1 Patient is less than 18 years of age

OR

3.2 Both of the following:

- Patient is 18 years of age or older
- Patient is continuing therapy [C]

AND

4 - Patient is able to swallow a capsule whole

Product Name: Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KOSELUGO	SELUMETINIB SULFATE CAP 10 MG	21533565500110	Brand
KOSELUGO	SELUMETINIB SULFATE CAP 25 MG	21533565500125	Brand

Approval Criteria

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

3 . Endnotes

A. The initial authorization duration of 6 months is to allow for assessment of adverse reactions (e.g., cardiomyopathy) without interruption of therapy [1,2].
B. Inoperable plexiform neurofibromas are defined as those that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN [1].
C. It is the recommendation of the consultant that the medication should not be discontinued due to patient's age [2].

4 . References

1. Koselugo Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. January 2024.
2. Per clinical consult with oncologist, May 27, 2020.

5 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160889
Guideline Name	Lenvima (lenvatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy. 2) Indicated as first-line treatment of adult patients with advanced RCC in combination with pembrolizumab. **Hepatocellular Carcinoma** Indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC). **Endometrial Carcinoma** In combination with pembrolizumab, is indicated for the treatment of patients with advanced endometrial carcinoma (EC) that is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or not microsatellite instability-high (MSI-

H), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation

2 . Criteria

Product Name: Lenvima	
Diagnosis	Differentiated thyroid cancer (DTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LENVIMA 4 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)	2133505420B210	Brand
LENVIMA 8 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)	2133505420B215	Brand
LENVIMA 10 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)	2133505420B220	Brand
LENVIMA 12MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)	2133505420B223	Brand
LENVIMA 20 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)	2133505420B230	Brand
LENVIMA 14 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)	2133505420B240	Brand
LENVIMA 18 MG DAILY DOSE	LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE)	2133505420B244	Brand
LENVIMA 24 MG DAILY DOSE	LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE)	2133505420B250	Brand

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC) [A]

Product Name: Lenvima	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LENVIMA 4 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)	2133505420B210	Brand
LENVIMA 8 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)	2133505420B215	Brand
LENVIMA 10 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)	2133505420B220	Brand
LENVIMA 12MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)	2133505420B223	Brand
LENVIMA 20 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)	2133505420B230	Brand
LENVIMA 14 MG DAILY DOSE	LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)	2133505420B240	Brand
LENVIMA 18 MG DAILY DOSE	LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE)	2133505420B244	Brand
LENVIMA 24 MG DAILY DOSE	LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE)	2133505420B250	Brand

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following:

2.1 Both of the following*: [4]

- Treatment follows one prior anti-angiogenic therapy [e.g., Inlyta (axitinib), Votrient (pazopanib), Nexavar (sorafenib), Sutent (sunitinib)]
- Used in combination with Afinitor (everolimus) for clear cell renal cell carcinoma [B]

OR

2.2 Both of the following*: [4]

- Used as first-line treatment for clear cell renal cell carcinoma
- Used in combination with Keytruda (pembrolizumab)

OR

2.3 One of the following:

2.3.1 Both of the following: [4]

- Used in the treatment of non-clear cell renal cell carcinoma
- Trial and failure, contraindication or intolerance to generic sunitinib

OR

2.3.2 For continuation of prior therapy

Notes	*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 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 advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

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

AND

5 - Prescribed by or in consultation with an oncologist

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]
B. NCCN recognizes use for subsequent therapy in combination with everolimus for relapse or for surgically unresectable stage IV disease with predominant clear cell histology that progressed on prior antiangiogenic therapy. [2]

4 . References

1. Lenvima Prescribing Information. Eisai Inc. Nutley, NJ. November 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 2, 2019.
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. V1.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed July 20, 2022.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-158729
Guideline Name	Leukotriene Modifiers
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zyflo (zileuton)
Asthma Indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Zyflo is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. Therapy with Zyflo can be continued during acute exacerbations of asthma.
Drug Name: Zileuton extended-release
Asthma Indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Zileuton extended-release tablet is not indicated for use in the reversal of bronchospasm in acute asthma attacks. Therapy with zileuton extended-release tablet can be continued during acute exacerbations of asthma.

2 . Criteria

Product Name: Zyflo, Generic zileuton ER	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ZYFLO	ZILEUTON TAB 600 MG	44504085000330	Brand
ZILEUTON ER	ZILEUTON TAB SR 12HR 600 MG	44504085007420	Generic

Approval Criteria

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

AND

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

- montelukast
- zafirlukast

3 . References

1. Zyflo [prescribing Information]. Cary, NC: Chiesi USA, Inc; January 2022.
2. Zileuton Extended-Release [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc; August 2020

Prior Authorization Guideline

Guideline ID	GL-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-160890
Guideline Name	Long-Acting Bronchodilator Combinations - PA, ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Airduo Respiclick (fluticasone propionate and salmeterol) Inhalation Powder, Airduo Digihaler (fluticasone propionate and salmeterol) Inhalation Powder
Asthma Indicated for the treatment of asthma in patients aged 12 years and older. Airduo should be used for patients not adequately controlled on a long term asthma control medication such as an inhaled corticosteroid or whose disease warrants initiation of treatment with both an inhaled corticosteroid and long acting beta-2 adrenergic agonist (LABA). Limitations of Use: Airduo is NOT indicated for the relief of acute bronchospasm.
Drug Name: Bevespi Aerosphere (glycopyrrolate and formoterol fumarate)
Chronic Obstructive Pulmonary Disease (COPD) Indicated for the long-term, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Limitation of use: Bevespi Aerosphere is not indicated for the relief of acute bronchospasm or for the treatment of asthma.
Drug Name: Dulera (mometasone/formoterol) Inhalation Aerosol

Asthma Indicated for the treatment of asthma in patients 5 years of age and older. Dulera should be used for patients not adequately controlled on a long-term asthma-control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an ICS and long-acting beta-2-adrenergic agonist (LABA). Limitation of Use: Dulera is not indicated for the relief of acute bronchospasm.
Drug Name: Duaklir Pressair (aclidinium bromide and formoterol fumarate)
Chronic Obstructive Pulmonary Disease (COPD) Indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Limitations of Use: Not indicated for the relief of acute bronchospasm or for the treatment of asthma.
Drug Name: Wixela Inhub (fluticasone/salmeterol) Inhalation Powder
Asthma Indicated for twice-daily treatment of asthma in patients aged 4 years and older. Wixela Inhub should be used for patients not adequately controlled on a long-term asthma control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an ICS and long-acting beta - adrenergic agonist (LABA). Limitations of Use: Wixela Inhub is NOT indicated for the relief of acute bronchospasm **Chronic Obstructive Pulmonary Disease (COPD)** Maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Limitations of Use: Wixela Inhub is NOT indicated for the relief of acute bronchospasm.
Drug Name: Symbicort (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol, Breyna (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol
Asthma Indicated for the treatment of asthma in patients 6 years of age and older. Symbicort should be used for patients not adequately controlled on a long-term asthma-control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an inhaled corticosteroid and long-acting beta2-adrenergic agonist (LABA). **Chronic Obstructive Pulmonary Disease** Maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema. Limitations of Use: Not indicated for the relief of acute bronchospasm.

2 . Criteria

Product Name: Bevespi, Duaklir Pressair	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
BEVESPI AEROSPHERE	GLYCOPYRROLATE-FORMOTEROL FUMARATE AEROSOL 9-4.8 MCG/ACT	44209902543220	Brand
DUAKLIR PRESSAIR	ACLIDINIUM BR-FORMOTEROL FUM AERO POW BR ACT 400-12 MCG/ACT	44209902268030	Brand

Approval Criteria

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

AND

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

- Anoro Ellipta
- Stiolto Respimat

Product Name: Brand Airduo Respiclick, Brand fluticasone propionate/salmeterol (Airduo Resplick ABA), Airduo Digihaler, Brand Advair Diskus, Brand Symbicort	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
AIRDUO RESPICLICK 55/14	FLUTICASONE-SALMETEROL AER POWDER BA 55-14 MCG/ACT	44209902708010	Generic
AIRDUO RESPICLICK 113/14	FLUTICASONE-SALMETEROL AER POWDER BA 113-14 MCG/ACT	44209902708015	Generic
AIRDUO RESPICLICK 232/14	FLUTICASONE-SALMETEROL AER POWDER BA 232-14 MCG/ACT	44209902708025	Generic
FLUTICASONE PROPIONATE/SALMETEROL	FLUTICASONE-SALMETEROL AER POWDER BA 55-14 MCG/ACT	44209902708010	Generic
FLUTICASONE PROPIONATE/SALMETEROL	FLUTICASONE-SALMETEROL AER POWDER BA 113-14 MCG/ACT	44209902708015	Generic
FLUTICASONE PROPIONATE/SALMETEROL	FLUTICASONE-SALMETEROL AER POWDER BA 232-14 MCG/ACT	44209902708025	Generic

AIRDUO DIGIHALER 55/14	FLUTICASONE-SALMETEROL AER POWDER BA 55-14 MCG/ACT W/ SENSOR	44209902718020	Brand
AIRDUO DIGIHALER 113/14	FLUTICASONE-SALMETEROL AER POWDER BA 113-14 MCG/ACT W/SENSOR	44209902718030	Brand
AIRDUO DIGIHALER 232/14	FLUTICASONE-SALMETEROL AER POWDER BA 232-14 MCG/ACT W/SENSOR	44209902718040	Brand
SYMBICORT	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 80-4.5 MCG/ACT	44209902413220	Brand
SYMBICORT	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 160-4.5 MCG/ACT	44209902413240	Brand
ADVAIR DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 100-50 MCG/ACT	44209902708020	Brand
ADVAIR DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 250-50 MCG/ACT	44209902708030	Brand
ADVAIR DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 500-50 MCG/ACT	44209902708040	Brand

Approval Criteria

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

AND

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

- Advair HFA (fluticasone/salmeterol)
- Breo Ellipta (fluticasone/vilanterol)
- Symbicort (budesonide/formoterol)^

Notes	^Brand product may be excluded, please consult client-specific resources to confirm formulary coverage. Recommend brand or generic product based on lower tier product.

Product Name: Dulera	
Approval Length	12 month(s)

Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 100-5 MCG/ACT	44209902903220	Brand
DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 200-5 MCG/ACT	44209902903240	Brand
DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 50-5 MCG/ACT	44209902903210	Brand

Approval Criteria

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

AND

2 - One of the following:

2.1 Patient is 5 years of age

OR

2.2 All of the following:

2.2.1 Patient is 6 years of age to 12 years of age

AND

2.2.2 Trial and failure (of a minimum 30-day supply) or intolerance to Symbicort (budesonide/formoterol)^

AND

2.2.3 One of the following:

2.2.3.1 Trial and failure (of a minimum 30-day supply) or intolerance to Breo Ellipta (fluticasone/vilanterol)

OR

2.2.3.2 Patient requires a metered dose inhaler used with a spacer device due to one of the following:

- Physical dexterity
- Inspiratory flow
- Cognitive status

OR

2.3 Both of the following:

2.3.1 Patient is 12 years of age or older

AND

2.3.2 Trial and failure (of a minimum 30-day supply) or intolerance to any two of the following:

- Advair HFA (fluticasone/salmeterol)
- Breo Ellipta (fluticasone/vilanterol)
- Symbicort (budesonide/formoterol)^

Notes	^Brand product may be excluded, please consult client-specific resources to confirm formulary coverage. Recommend brand or generic product based on lower tier product.

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

Product Name	Generic Name	GPI	Brand/Generic
DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 100-5 MCG/ACT	44209902903220	Brand

DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 200-5 MCG/ACT	44209902903240	Brand
DULERA	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 50-5 MCG/ACT	44209902903210	Brand

Approval Criteria

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

AND

2 - One of the following:

2.1 Patient is 5 years of age

OR

2.2 All of the following:

2.2.1 Patient is 6 years of age to 12 years of age

AND

2.2.2 Submission of chart notes (e.g., chart notes) or paid claims confirming trial and failure (of a minimum 30-day supply) or intolerance to Symbicort (budesonide/formoterol)^

AND

2.2.3 Submission of chart notes (e.g., chart notes) and/or paid claims confirming one of the following:

2.2.3.1 Trial and failure (of a minimum 30-day supply) or intolerance to Breo Ellipta (fluticasone/vilanterol)

OR

2.2.3.2 Patient requires a metered dose inhaler used with a spacer device due to one of the following:

- Physical dexterity
- Inspiratory flow
- Cognitive status

OR

2.3 Both of the following:

2.3.1 Patient is 12 years of age or older

AND

2.3.2 Submission of chart notes (e.g., chart notes) and/or paid claims confirming trial and failure (of a minimum 30-day supply) or intolerance to any two of the following:

- Advair HFA (fluticasone/salmeterol)
- Breo Ellipta (fluticasone/vilanterol)
- Symbicort (budesonide/formoterol)^

Notes	^Brand product may be excluded, please consult client-specific resources to confirm formulary coverage. Recommend brand or generic product based on lower tier product.

Product Name: Generic budesonide/formoterol, Breyna	
Approval Length	12 month(s)
Guideline Type	Prior Authorization, Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
BUDESONIDE/FORMOTEROL FUMARATE DIHYDRATE	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 80-4.5 MCG/ACT	44209902413220	Generic
BREYNA	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 80-4.5 MCG/ACT	44209902413220	Generic
BUDESONIDE/FORMOTEROL FUMARATE DIHYDRATE	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 160-4.5 MCG/ACT	44209902413240	Generic

BREYNA	BUDESONIDE-FORMOTEROL FUMARATE DIHYD AEROSOL 160-4.5 MCG/ACT	44209902413240	Generic

Approval Criteria

1 - One of the following:

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

OR

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

AND

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

AND

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

Product Name: Generic fluticasone/salmeterol powder, Wixela Inhub	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
FLUTICASONE PROPIONATE/SALMETEROL DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 100-50 MCG/DOSE	44209902708020	Generic
WIXELA INHUB	FLUTICASONE-SALMETEROL AER POWDER BA 100-50 MCG/DOSE	44209902708020	Generic
FLUTICASONE PROPIONATE/SALMETEROL	FLUTICASONE-SALMETEROL AER POWDER BA 100-50 MCG/DOSE	44209902708020	Generic

FLUTICASONE PROPIONATE/SALMETEROL DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 250-50 MCG/DOSE	44209902708030	Generic
WIXELA INHUB	FLUTICASONE-SALMETEROL AER POWDER BA 250-50 MCG/DOSE	44209902708030	Generic
FLUTICASONE PROPIONATE/SALMETEROL	FLUTICASONE-SALMETEROL AER POWDER BA 250-50 MCG/DOSE	44209902708030	Generic
FLUTICASONE PROPIONATE/SALMETEROL DISKUS	FLUTICASONE-SALMETEROL AER POWDER BA 500-50 MCG/DOSE	44209902708040	Generic
WIXELA INHUB	FLUTICASONE-SALMETEROL AER POWDER BA 500-50 MCG/DOSE	44209902708040	Generic

Approval Criteria

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

AND

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

- Advair HFA (fluticasone/salmeterol)
- Breo Ellipta (fluticasone/vilanterol)
- Brand Symbicort

3 . References

1. Dulera Prescribing Information. Merck & Co., Inc. Whitehouse, NJ. March 2023.
2. Bevespi Aerosphere Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. March 2023.
3. Airduo Respiclick Prescribing Information. Teva Respiratory, LLC. Frazer, PA. February 2024.
4. Airduo Digihaler Prescribing Information. Teva Respiratory, LLC. Frazer, PA. January 2023.
5. Duaklir Pressair Prescribing Information. Circassia Pharmaceuticals Inc. Morrisville, NC. January 2022.
6. Wixela inhub Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. August 2022

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160891
Guideline Name	Lynparza (olaparib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Lynparza (olaparib)
First-line maintenance treatment of BRCA-mutated advanced ovarian cancer Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAmor sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. **Maintenance treatment of BRCA-mutated recurrent ovarian cancer** Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. **First-line maintenance treatment of HRD-positive advanced ovarian cancer in combination with bevacizumab** Indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or

primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Germline BRCA-mutated HER2-negative high risk early breast cancer Indicated for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCA-mutated, HER2-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Germline BRCA-mutated HER2-negative metastatic breast cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious gBRCA-mutated, HER2-negative metastatic breast cancer, who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

First-line maintenance treatment of germline BRCA-mutated metastatic pancreatic adenocarcinoma Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

HRR gene-mutated metastatic castration-resistant prostate cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) Indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

2 . Criteria

Product Name: Lynparza	
Diagnosis	Epithelial ovarian, Fallopian tube, or Primary peritoneal cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYNPARZA	OLAPARIB TAB 100 MG	21535560000330	Brand
LYNPARZA	OLAPARIB TAB 150 MG	21535560000340	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

Product Name: Lynparza	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYNPARZA	OLAPARIB TAB 100 MG	21535560000330	Brand
LYNPARZA	OLAPARIB TAB 150 MG	21535560000340	Brand

Approval Criteria

1 - Diagnosis of breast cancer

Product Name: Lynparza	
Diagnosis	Pancreatic adenocarcinoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYNPARZA	OLAPARIB TAB 100 MG	21535560000330	Brand
LYNPARZA	OLAPARIB TAB 150 MG	21535560000340	Brand

Approval Criteria

1 - Diagnosis pancreatic adenocarcinoma

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

Product Name	Generic Name	GPI	Brand/Generic
LYNPARZA	OLAPARIB TAB 100 MG	21535560000330	Brand
LYNPARZA	OLAPARIB TAB 150 MG	21535560000340	Brand

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)

AND

2 - Presence of a deleterious or suspected deleterious BRCA-mutation or homologous recombination repair (HRR) gene mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - For BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC), Lynparza is used in combination with abiraterone and one of the following:

- prednisone
- prednisolone

Product Name: Lynparza	
Diagnosis	All Indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LYNPARZA	OLAPARIB TAB 100 MG	21535560000330	Brand
LYNPARZA	OLAPARIB TAB 150 MG	21535560000340	Brand

Approval Criteria

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

3 . References

1. Lynparza Tablets prescribing information. AstraZeneca Pharmaceuticals LP, Inc. Wilmington, DE. November 2023.
2. Lynparza FDA Medical Review. http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206162Orig1s000MedR.pdf. Accessed on June 12, 2015.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 9, 2021.
4. Robson M, Im SA, Senkus E, et al. Olaparib for Metastatic Breast Cancer in Patients with a Germline BRCA Mutation. N Engl J Med. 2017 Aug 10;377(6):523-533
5. U.S. Food and Drug Administration [website]: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm Accessed 3/7/2018

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160892
Guideline Name	Mavyret (glecaprevir/pibrentasvir)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Mavyret (glecaprevir/pibrentasvir)
Chronic Hepatitis C (CHC) Indicated for the treatment of adult and pediatric patients 3 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). Indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

2 . Criteria

Product Name: Mavyret (glecaprevir/pibrentasvir)

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Naïve; without Decompensated Cirrhosis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is treatment-naive

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1; Treatment-Experienced (Prior failure to an NS3/4A Protease Inhibitor); without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient has experienced failure with a previous treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

- Hepatologist

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1; Treatment-Experienced (Prior failure to an NS5A Inhibitor); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 3; Treatment-Experienced (Interferon- or Sovaldi-based Regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 3

AND

2 - Patient has experienced treatment failure with a previous treatment regimen that included interferon, peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); without Cirrhosis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without cirrhosis

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); with Compensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient has compensated cirrhosis (e.g., Child-Pugh Class A)

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Sovaldi-based regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous treatment regimen that included Sovaldi (sofosbuvir)

AND

3 - Patient has had no previous treatment experience with an HCV NS3/4A protease inhibitor inclusive combination direct acting antiviral regimen (e.g., Zepatier [elbasvir/grazoprevir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Mavyret); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Mavyret (glecaprevir/pibrentasvir) [2]

AND

3 - Used in combination with Sovaldi (sofosbuvir) and ribavirin [2]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Vosevi); without Decompensated Cirrhosis

Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [2]

AND

3 - Used in combination with Sovaldi (sofosbuvir) and ribavirin [2]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 Post-Liver or Kidney Transplant; Treatment-Naive or Treatment-Experienced (Non-Direct-Acting Antiviral); without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has had a liver or kidney transplant [2]

AND

3 - One of the following:

- Patient is treatment-naive
- Patient has previously received non-direct-acting antiviral treatment (e.g., peginterferon)

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; HCV-Uninfected Recipients of a Liver Transplant from HCV-Viremic Donors; without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Both of the following [2]:

- Patient was not infected with HCV prior to receiving a liver transplant
- Patient received a liver transplant from a donor with a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

4 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; HCV-Uninfected Recipients of Non-Liver Organ Transplant from HCV-Viremic Donors; without Decompensated Cirrhosis; within First Week After Transplant
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand
MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Both of the following [2]:

- Patient was not infected with HCV prior to receiving a non-liver organ transplant

- Patient received a non-liver organ transplant from a donor with a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Treatment initiation will occur no later than the first week after transplant

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; HCV-Uninfected Recipients of Non-Liver Organ Transplant from HCV-Viremic Donors; without Decompensated Cirrhosis; beyond First Week After Transplant
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVYRET	GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG	12359902350320	Brand

MAVYRET	GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG	12359902353020	Brand

Approval Criteria

1 - Both of the following [2]:

- Patient was not infected with HCV prior to receiving a non-liver organ transplant
- Patient received a non-liver organ transplant from a donor with a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Treatment initiation will occur beyond the first week after transplant

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

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

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

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

3 . References

1. Mavyret Prescribing Information. Abbvie Inc. North Chicago, IL. October 2023.

2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160893
Guideline Name	Mekinist (trametinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Mekinist (trametinib)
BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma Indicated, as a single agent in BRAF-inhibitor treatment-naïve patients or in combination with dabrafenib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. **BRAF V600E mutation-positive metastatic non-small cell lung cancer** Indicated, in combination with dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer with BRAF V600E mutation as detected by an FDA-approved test. **Adjuvant treatment of BRAF V600E or V600K mutation-positive melanoma** Indicated, in combination with dabrafenib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node (s), following complete resection. **BRAF V600E mutation-positive locally advanced or metastatic anaplastic thyroid cancer** Indicated, in combination with dabrafenib, for the treatment of patients with locally

advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional options.

BRAF V600E mutation-positive unresectable or metastatic solid tumors Indicated, in combination with dabrafenib, for the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

BRAF V600E mutation-positive low-grade glioma Indicated, in combination with dabrafenib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

Limitations of Use MEKINIST is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition.

2 . Criteria

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - One of the following diagnoses: [2]

- Unresectable melanoma
- Metastatic melanoma

AND

2 - Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

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

Product Name: Mekinist	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand

MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer

AND

2 - Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

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

Product Name: Mekinist	
Diagnosis	Adjuvant treatment for melanoma
Approval Length	12 Month [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Cancer is BRAF V600E mutation or V600K mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Involvement of lymph nodes following complete resection [2]

AND

4 - Used as adjunctive therapy

AND

5 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) [4]

AND

2 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Cancer may not be treated with standard locoregional treatment options

AND

4 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

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

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Patient is 1 year of age or older

AND

3 - Disease is one of the following:

- unresectable
- metastatic

AND

4 - Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options

AND

5 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand

MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

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

Product Name: Mekinist	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

1 - Diagnosis of low-grade glioma

AND

2 - Patient is 1 year of age or older

AND

3 - Patient requires systemic therapy

AND

4 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)	21533570100310	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)	21533570100330	Brand
MEKINIST	TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)	21533570102120	Brand

Approval Criteria

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

3 . Endnotes

A. The recommended dosage of MEKINIST is 2 mg orally taken once daily in combination with dabrafenib until disease recurrence or unacceptable toxicity for up to 1 year for the adjuvant treatment of melanoma [1].

4 . References

1. Mekinist Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2023.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Melanoma v.3.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed February 11, 2024.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer v.2.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 11, 2024.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma v.1.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed February 11 2024.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160894
Guideline Name	Migraine Quantity Limit
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan) tablets and nasal spray, Onzetra (sumatriptan), Relpax (eletriptan), Tosymra (sumatriptan), Zembrace SymTouch (sumatriptan), Zomig (zolmitriptan) tablets, Zomig-ZMT (zolmitriptan)
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Safety and effectiveness of respective triptan therapy have not been established for cluster headache (not applicable to Zembrace SymTouch). Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with therapy, reconsider the diagnosis of migraine before therapy is administered to treat any subsequent attacks. Therapy is not indicated for the prevention of migraine attacks.
Drug Name: Axert (almotriptan)
Migraine Headaches Indicated for the acute treatment of migraine attacks in adults with a history of migraine with or without aura. Indicated for the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine attacks with or

without aura usually lasting 4 hours or more (when untreated). Important Limitations: Only use where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

Drug Name: Maxalt (rizatriptan), Maxalt-MLT (rizatriptan)

Migraine headaches Indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old. Limitations of Use: Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine. Maxalt is not indicated for the prevention of migraine attacks. Safety and effectiveness of Maxalt have not been established for cluster headache.

Drug Name: Migranal (dihydroergotamine mesylate)

Migraine Headaches Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

Drug Name: Treximet (sumatriptan/naproxen)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age or older. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.

Drug Name: Zomig (zolmitriptan) nasal spray

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

Drug Name: D.H.E. 45 (dihydroergotamine mesylate) injection

Migraine Headache Indicated for the acute treatment of migraine headaches with or without aura. **Cluster Headaches** Indicated for acute treatment of cluster headache episodes.
Drug Name: Imitrex (sumatriptan) injection
Migraine Headache Indicated in adults for the acute treatment of migraine, with or without aura. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of migraine headache attacks. **Cluster Headaches** Indicated in adults for the acute treatment of cluster headache. Limitations of Use: Use only if a clear diagnosis of cluster headache has been established. If a patient has no response to the first cluster headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of cluster headache attacks.
Drug Name: Trudhesa (dihydroergotamine mesylate)
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine or for the management of hemiplegic or basilar migraine
Drug Name: Nurtec ODT (rimegepant sulfate)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. **Preventive Treatment of Episodic Migraine** Indicated for the preventive treatment of episodic migraine in adults.
Drug Name: Ubrelvy (ubrogepant)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.
Drug Name: Zavzpret (zavegepant)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name: Brand Amerge, Generic naratriptan, Brand Axert, Generic almotriptan, Brand Frova, Generic frovatriptan, Brand Imitrex, Generic sumatriptan, Brand Maxalt, Generic rizatriptan, Onzetra, Brand Relpax, Generic eletriptan, Tosymra, Brand Treximet, Generic sumatriptan/naproxen, Zembrace SymTouch, Brand Zomig, Generic zolmitriptan, or Brand Zolmitriptan nasal spray	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
IMITREX STATDOSE SYSTEM	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 6 MG/0.5ML	6740607010D520	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 6 MG/0.5ML	6740607010D520	Generic
NARATRIPTAN HCL	NARATRIPTAN HCL TAB 1 MG (BASE EQUIV)	67406050100310	Generic
AMERGE	NARATRIPTAN HCL TAB 1 MG (BASE EQUIV)	67406050100310	Brand
NARATRIPTAN HCL	NARATRIPTAN HCL TAB 2.5 MG (BASE EQUIV)	67406050100320	Generic
AMERGE	NARATRIPTAN HCL TAB 2.5 MG (BASE EQUIV)	67406050100320	Brand
ALMOTRIPTAN MALATE	ALMOTRIPTAN MALATE TAB 6.25 MG	67406010100320	Generic
AXERT	ALMOTRIPTAN MALATE TAB 6.25 MG	67406010100320	Brand
ALMOTRIPTAN MALATE	ALMOTRIPTAN MALATE TAB 12.5 MG	67406010100330	Generic
AXERT	ALMOTRIPTAN MALATE TAB 12.5 MG	67406010100330	Brand
FROVA	FROVATRIPTAN SUCCINATE TAB 2.5 MG (BASE EQUIVALENT)	67406030100320	Brand
FROVATRIPTAN SUCCINATE	FROVATRIPTAN SUCCINATE TAB 2.5 MG (BASE EQUIVALENT)	67406030100320	Generic
IMITREX	SUMATRIPTAN NASAL SPRAY 5 MG/ACT	67406070002010	Generic
SUMATRIPTAN	SUMATRIPTAN NASAL SPRAY 5 MG/ACT	67406070002010	Generic
IMITREX	SUMATRIPTAN NASAL SPRAY 20 MG/ACT	67406070002040	Brand
SUMATRIPTAN	SUMATRIPTAN NASAL SPRAY 20 MG/ACT	67406070002040	Generic
IMITREX STATDOSE SYSTEM	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 4 MG/0.5ML	6740607010D510	Brand

SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 4 MG/0.5ML	6740607010D510	Generic
IMITREX STATDOSE REFILL	SUMATRIPTAN SUCCINATE SOLUTION CARTRIDGE 4 MG/0.5ML	6740607010E210	Brand
SUMATRIPTAN SUCCINATE REFILL	SUMATRIPTAN SUCCINATE SOLUTION CARTRIDGE 4 MG/0.5ML	6740607010E210	Generic
IMITREX STATDOSE REFILL	SUMATRIPTAN SUCCINATE SOLUTION CARTRIDGE 6 MG/0.5ML	6740607010E220	Brand
SUMATRIPTAN SUCCINATE REFILL	SUMATRIPTAN SUCCINATE SOLUTION CARTRIDGE 6 MG/0.5ML	6740607010E220	Generic
IMITREX	SUMATRIPTAN SUCCINATE TAB 25 MG	67406070100305	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE TAB 25 MG	67406070100305	Generic
IMITREX	SUMATRIPTAN SUCCINATE TAB 50 MG	67406070100310	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE TAB 50 MG	67406070100310	Generic
IMITREX	SUMATRIPTAN SUCCINATE TAB 100 MG	67406070100320	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE TAB 100 MG	67406070100320	Generic
IMITREX	SUMATRIPTAN SUCCINATE INJ 6 MG/0.5ML	67406070102010	Brand
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE INJ 6 MG/0.5ML	67406070102010	Generic
RELPAX	ELETRIPTAN HYDROBROMIDE TAB 20 MG (BASE EQUIVALENT)	67406025100320	Brand
RELPAX	ELETRIPTAN HYDROBROMIDE TAB 40 MG (BASE EQUIVALENT)	67406025100340	Brand
RIZATRIPTAN BENZOATE	RIZATRIPTAN BENZOATE TAB 5 MG (BASE EQUIVALENT)	67406060100310	Generic
MAXALT	RIZATRIPTAN BENZOATE TAB 5 MG (BASE EQUIVALENT)	67406060100310	Brand
RIZATRIPTAN BENZOATE	RIZATRIPTAN BENZOATE TAB 10 MG (BASE EQUIVALENT)	67406060100320	Generic
MAXALT	RIZATRIPTAN BENZOATE TAB 10 MG (BASE EQUIVALENT)	67406060100320	Brand
MAXALT-MLT	RIZATRIPTAN BENZOATE ORAL DISINTEGRATING TAB 5 MG (BASE EQ)	67406060107220	Brand
RIZATRIPTAN BENZOATE ODT	RIZATRIPTAN BENZOATE ORAL DISINTEGRATING TAB 5 MG (BASE EQ)	67406060107220	Generic

MAXALT-MLT	RIZATRIPTAN BENZOATE ORAL DISINTEGRATING TAB 10 MG (BASE EQ)	67406060107230	Brand
RIZATRIPTAN BENZOATE ODT	RIZATRIPTAN BENZOATE ORAL DISINTEGRATING TAB 10 MG (BASE EQ)	67406060107230	Generic
TREXIMET	SUMATRIPTAN-NAPROXEN SODIUM TAB 85-500 MG	67992002600320	Brand
ZEMBRACE SYMTOUCH	SUMATRIPTAN SUCCINATE SOLUTION AUTO-INJECTOR 3 MG/0.5ML	6740607010D505	Brand
ZOMIG	ZOLMITRIPTAN TAB 2.5 MG	67406080000320	Brand
ZOLMITRIPTAN	ZOLMITRIPTAN TAB 2.5 MG	67406080000320	Generic
ZOMIG	ZOLMITRIPTAN TAB 5 MG	67406080000330	Brand
ZOLMITRIPTAN	ZOLMITRIPTAN TAB 5 MG	67406080000330	Generic
ZOMIG	ZOLMITRIPTAN NASAL SPRAY 2.5 MG/SPRAY UNIT	67406080002010	Brand
ZOMIG NASAL SPRAY	ZOLMITRIPTAN NASAL SPRAY 5 MG/SPRAY UNIT	67406080002020	Brand
ZOMIG ZMT	ZOLMITRIPTAN ORALLY DISINTEGRATING TAB 2.5 MG	67406080007220	Brand
ZOLMITRIPTAN ODT	ZOLMITRIPTAN ORALLY DISINTEGRATING TAB 2.5 MG	67406080007220	Generic
ZOMIG ZMT	ZOLMITRIPTAN ORALLY DISINTEGRATING TAB 5 MG	67406080007230	Brand
ZOLMITRIPTAN ODT	ZOLMITRIPTAN ORALLY DISINTEGRATING TAB 5 MG	67406080007230	Generic
ONZETRA	SUMATRIPTAN SUCCINATE EXHALER POWDER 11 MG/NOSEPIECE	6740607010G420	Brand
TREXIMET	SUMATRIPTAN-NAPROXEN SODIUM TAB 10-60 MG	67992002600305	Brand
ELETRIPTAN HYDROBROMIDE	ELETRIPTAN HYDROBROMIDE TAB 20 MG (BASE EQUIVALENT)	67406025100320	Generic
ELETRIPTAN HYDROBROMIDE	ELETRIPTAN HYDROBROMIDE TAB 40 MG (BASE EQUIVALENT)	67406025100340	Generic
SUMATRIPTAN/NAPROXEN SODIUM	SUMATRIPTAN-NAPROXEN SODIUM TAB 85-500 MG	67992002600320	Generic
ZOLMITRIPTAN	ZOLMITRIPTAN NASAL SPRAY 2.5 MG/SPRAY UNIT	67406080002010	Generic
ZOLMITRIPTAN	ZOLMITRIPTAN NASAL SPRAY 5 MG/SPRAY UNIT	67406080002020	Generic
TOSYMRA	SUMATRIPTAN NASAL SPRAY 10 MG/ACT	67406070002020	Brand

Approval Criteria

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

AND

2 - Patient is experiencing 2 or more headaches per month [10-12]

AND

3 - Patient will not be treating 15 or more headache days per month

AND

4 - Currently receiving prophylactic therapy with at least one of the following: [A, 10, 24]

- An antidepressant (i.e., Elavil [amitriptyline] or Effexor [venlafaxine])
- An anticonvulsant (i.e., Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate])
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- An angiotensin receptor blocker (i.e., Atacand [candesartan])
- An angiotensin-converting enzyme (ACE) inhibitor (i.e., lisinopril)

AND

5 - Not used in combination with another triptan-containing product

AND

6 - One of the following: [B]

6.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer’s prescribing information

OR

6.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Product Name: Brand D.H.E. 45, Generic dihydroergotamine mesylate injection, Brand Migranal, Generic dihydroergotamine mesylate nasal spray, Nurtec ODT, Trudhesa, Ubrelvy, Zavzpret

Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Generic
MIGRANAL	DIHYDROERGOTAMINE MESYLATE NASAL SPRAY 4 MG/ML	67000030102060	Brand
DIHYDROERGOTAMINE MESYLATE	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Generic
D.H.E. 45	DIHYDROERGOTAMINE MESYLATE INJ 1 MG/ML	67000030102005	Brand
TRUDHESA	DIHYDROERGOTAMINE MESYLATE HFA NASAL AEROSOL 0.725 MG/ACT	67000030113420	Brand
UBRELVY	UBROGEPANT TAB 50 MG	67701080000320	Brand
UBRELVY	UBROGEPANT TAB 100 MG	67701080000340	Brand
NURTEC	RIMEGEPANT SULFATE TAB DISINT 75 MG	67701060707220	Brand
ZAVZPRET	ZAVEGEPANT HCL NASAL SPRAY 10 MG/ACT	67701090202020	Brand

Approval Criteria

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

AND

2 - One of the following: [B]

2.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer's prescribing information

OR

2.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

3 . Endnotes

A. The American Academy of Neurology and American Headache Society support the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], candesartan, and lisinopril. [10, 25]
B. Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

4 . References

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4. Imitrex Tablets Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2020.
5. Imitrex Nasal Spray Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2017.
6. Imitrex Injection Prescribing Information. GlaxoSmithKline. Durham, NC. February 2023.
7. Maxalt/Maxalt MLT Prescribing Information. Organon LLC. Jersey City, NJ. June 2021.

8. Migranal Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2022.
9. Relpax Prescribing Information. Roerig. New York, NY. March 2020.
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13. Onzetra Xsail Prescribing Information. Currax Pharmaceuticals LLC. Morristown, NJ. December 2019.
14. Treximet Prescribing Information. Currax Pharmaceuticals LLC. Brentwood, TN. January 2024.
15. Zomig/Zomig ZMT Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.
16. Zomig Nasal Spray Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.
17. D.H.E. 45 Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. April 2022.
18. Loder E, Burch R, Rizzoli P. The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A Summary and Comparison with Other Recent Clinical Practice Guidelines. Headache 2012;52:930-945.
19. Zembrace SymTouch Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN. February 2021.
20. Tosymra Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN. February 2021.
21. Trudhesa Prescribing Information. Impel NeuroPharma Inc. Seattle, WA. August 2023.
22. Nurtec ODT Prescribing Information. Pfizer Inc. New York, NY April 2023.
23. Ubrelvy Prescribing Information. AbbVie Inc. North Chicago, IL. June 2023.
24. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.
25. Zavzpret Prescribing Information. Pfizer Labs. New York, NY. March 2023.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160895
Guideline Name	Mitoxantrone
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Mitoxantrone
Multiple Sclerosis Indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (i.e., patients whose neurologic status is significantly abnormal between relapses). It is not indicated in the treatment of patients with primary progressive multiple sclerosis. **Prostate Cancer** Indicated, in combination with corticosteroids, as initial chemotherapy for the treatment of patients with pain related to advanced hormone-refractory prostate cancer. **Acute Non-Lymphocytic Leukemia (ANLL)** Indicated, in combination with other approved drug(s), in the initial therapy of ANLL in adults. This category includes myelogenous, promyelocytic, monocytic, and erythroid acute leukemias.

2 . Criteria

Product Name: Generic mitoxantrone	
Diagnosis	Multiple Sclerosis
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic

Approval Criteria

1 - Diagnosis of one of the following:

1.1 Secondary progressive multiple sclerosis: gradually worsening disability with or without superimposed relapses [2]

OR

1.2 Progressive relapsing multiple sclerosis: progression of disability from the onset with superimposed relapses [2]

OR

1.3 Worsening relapsing-remitting multiple sclerosis: neurological status remains significantly abnormal in between multiple sclerosis relapses [3]

AND

2 - Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two

disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod]): [B, 3, 11]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Neutrophil count greater than or equal to 1,500 cell/mm^3

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Generic mitoxantrone	
Diagnosis	Multiple Sclerosis
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140 mg/m^2 [1]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Generic mitoxantrone	
Diagnosis	Prostate Cancer
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic

Approval Criteria

1 - Diagnosis of advanced hormone-refractory (castration-resistant) prostate cancer

AND

2 - Used in combination with corticosteroids (e.g., prednisone, methylprednisolone) [7, 8, 10]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Neutrophil count greater than or equal to 1,500 cell/mm^3

Product Name: Generic mitoxantrone	
Diagnosis	Prostate Cancer
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic

Approval Criteria

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

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140mg/m^2 [1]

Product Name: Generic mitoxantrone	
Diagnosis	Acute Non-Lymphocytic Leukemia (ANLL)

Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic

Approval Criteria

1 - Diagnosis of acute non-lymphocytic leukemia (ANLL) (e.g., myelogenous, promyelocytic, monocytic, and erythroid)

AND

2 - Used in combination with other medications used for the treatment of ANLL [9, 10]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

Product Name: Generic mitoxantrone	
Diagnosis	Acute Non-Lymphocytic Leukemia (ANLL)
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 20 MG/10ML (2 MG/ML)	21200055001320	Generic
MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 25 MG/12.5ML (2 MG/ML)	21200055001325	Generic

MITOXANTRONE HCL	MITOXANTRONE HCL INJ CONC 30 MG/15ML (2 MG/ML)	21200055001330	Generic

Approval Criteria

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

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140mg/m^2 [1]

3 . Endnotes

A. All patients should be carefully assessed for cardiac signs and symptoms by history and physical examination prior to start of Novantrone therapy. Left ventricular ejection fraction (LVEF) should be evaluated prior to administration of the initial dose of mitoxantrone and all subsequent doses. Mitoxantrone is recommended to be dosed once every three months. Additional doses of mitoxantrone should not be administered to multiple sclerosis patients who have experienced either a drop in LVEF to below 50% or a clinically significant reduction in LVEF during mitoxantrone therapy. [1]
B. Per 2018 American Academy of Neurology (AAN) Multiple Sclerosis (MS) guideline, mitoxantrone should not be prescribed to people with MS due to the high frequency of severe adverse effects unless the potential benefit greatly outweighs the risk. Another MS agent that has relatively more side effects include Lemtrada and its prescribing information recommends reserving use after two prior lines of therapies have been tried. Due to this, a requirement of two prior agents for Mitoxantrone would be more appropriate to align with other MS agents that have more risks than benefit. [11]

4 . References

1. Mitoxantrone Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. December 2019.

2. Hartung HP, Gonsette R, Konig N, et al. Mitoxantrone in progressive multiple sclerosis: a placebo-controlled, double-blind, randomized, mulitcentre trial. Lancet 2002;360:2018-25.
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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-158736
Guideline Name	Multiple Sclerosis (MS) Agents - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Aubagio (teriflunomide), Avonex (interferon beta-1a), Bafiertam (monomethyl fumarate), Betaseron (interferon beta-1b), Briumvi (ublituximab-xiiy), Copaxone (glatiramer acetate), Extavia (interferon beta-1b), Glatopa (glatiramer acetate)
Relapsing forms of multiple sclerosis (MS) Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Kesimpta (ofatumumab), Mayzent (siponimod), Plegridy (peginterferon beta-1a), Ponvory (ponesimod), Rebif (interferon beta-1a), Vumerity (diroximel fumarate)
Relapsing forms of multiple sclerosis (MS) Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Lemtrada (alemtuzumab)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Limitations of Use: Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
Drug Name: Mavenclad (cladribine)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Limitations of Use: Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
Drug Name: Ocrevus (ocrelizumab)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. **Primary Progressive Forms of Multiple Sclerosis (PPMS)** Indicated for the treatment of primary progressive MS, in adults.
Drug Name: Tascenso ODT (fingolimod)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

2 . Criteria

Product Name: Brand Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone 40mg/mL, Generic glatiramer acetate, Glatopa, Kesimpta*, Mayzent, Generic Teriflunomide, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AUBAGIO	TERIFLUNOMIDE TAB 7 MG	62404070000320	Brand
AUBAGIO	TERIFLUNOMIDE TAB 14 MG	62404070000330	Brand

BETASERON	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Brand
AVONEX PEN	INTERFERON BETA-1A IM AUTO-INJECTOR KIT 30 MCG/0.5ML	6240306045F530	Brand
AVONEX	INTERFERON BETA-1A IM PREFILLED SYRINGE KIT 30 MCG/0.5ML	6240306045F830	Brand
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (12) STARTER PACK	6240707020B720	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 0.25 MG (BASE EQUIV)	62407070200320	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 2 MG (BASE EQUIV)	62407070200340	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DR STARTER BOTTLE 231 MG	62405530006520	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DELAYED RELEASE 231 MG	62405530006540	Brand
BAFIERTAM	MONOMETHYL FUMARATE CAPSULE DELAYED RELEASE 95 MG	62405550006520	Brand
KESIMPTA	OFATUMUMAB SOLN AUTO-INJECTOR 20 MG/0.4ML	6240506500D520	Brand
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (7) STARTER PACK	6240707020B710	
MAYZENT	SIPONIMOD FUMARATE TAB 1 MG (BASE EQUIV)	62407070200330	
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 7 MG	62404070000320	Generic
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 14 MG	62404070000330	Generic
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - For Brand Aubagio, trial and failure (of a minimum 4-week supply), or intolerance to generic teriflunomide

Notes	*For Kesimpta, there is a QL Override (For new starts only): Please e nter 2 PAs as follows with the same start date: First PA: Approve 3 syr inges or pens per 28 days for the first month (Loading dose has a MD D of 0.05); Second PA: Approve 1 syringe or pen per 28 days (no ove rrides needed) for 12 months. (Kesimpta is hard-coded with a quantity of 1 syringe or pen per 28 days; 0.4 mL per 20 mg pen or syringe. Ma intenance dose has a MDD of 0.02)

Product Name: Brand Copaxone 20mg/mL	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Trial and failure (of a minimum 4-week supply), or intolerance to generic glatiramer acetate

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PEN-INJECTOR 125 MCG/0.5ML	6240307530D520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK	6240307530D550	Brand
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PREFILLED SYRINGE 125 MCG/0.5ML	6240307530E520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PREF SYR 63 & 94 MCG/0.5ML PACK	6240307530E550	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 22 MCG/0.5ML (12MU/ML)	6240306045D520	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 44 MCG/0.5ML (24MU/ML)	6240306045D540	Brand
REBIF REBIDOSE TITRATION PACK	INTERFERON BETA-1A AUTO-INJ 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045D560	Brand

REBIF	INTERFERON BETA-1A SOLN PREF SYR 22 MCG/0.5ML (12MU/ML)	6240306045E520	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 44 MCG/0.5ML (24MU/ML)	6240306045E540	Brand
REBIF TITRATION PACK	INTERFERON BETA-1A PREF SYR 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045E560	Brand
EXTAVIA	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
PLEGRIDY	PEGINTERFERON BETA-1A IM SOLN PREFILLED SYR 125 MCG/0.5ML	6240307530E521	Brand
PONVORY 14-DAY STARTER PACK	PONESIMOD TAB STARTER PACK 2,3,4,5,6,7,8,9 &10 MG	6240706000B720	Brand
PONVORY	PONESIMOD TAB 20 MG	62407060000320	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 For continuation of therapy

OR

2.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Kesimpta (ofatumumab)
- Vumerity (diroximel fumarate)
- Mayzent (siponimod)

- Zeposia (ozanimod)

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

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

Product Name	Generic Name	GPI	Brand/Generic
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.25 MG	62407025207220	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.5 MG	62407025207230	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - Patient is 10 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 18 years of age or older

AND

3.1.2 One of the following:

3.1.2.1 For continuation of therapy

OR

3.1.2.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Kesimpta (ofatumumab)
- Dimethyl fumarate
- Fingolimod
- Mayzent (siponimod)
- Vumerity (diroximel fumarate)
- Zeposia (ozanimod)

OR

3.2 Both of the following:

3.2.1 Patient is younger than 18 years of age

AND

3.2.2 One of the following:

3.2.2.1 Both of the following:

- Patient weighs greater than or equal to 40kg

- Trial and failure (of a minimum 4-week supply) or intolerance to generic fingolimod

OR

3.2.2.2 Both of the following:

- Patient weighs less than 40kg
- Trial and failure (of a minimum 4-week supply) or intolerance to Gilenya (fingolimod)

AND

4 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Patient is unable to take oral tablets

Product Name: Brand Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone 40mg/mL, Extavia, Generic glatiramer acetate, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Generic Teriflunomide, Vumerity

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

Product Name	Generic Name	GPI	Brand/Generic
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PEN-INJECTOR 125 MCG/0.5ML	6240307530D520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK	6240307530D550	Brand
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PREFILLED SYRINGE 125 MCG/0.5ML	6240307530E520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PREF SYR 63 & 94 MCG/0.5ML PACK	6240307530E550	Brand

AUBAGIO	TERIFLUNOMIDE TAB 7 MG	62404070000320	Brand
AUBAGIO	TERIFLUNOMIDE TAB 14 MG	62404070000330	Brand
BETASERON	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 22 MCG/0.5ML (12MU/ML)	6240306045D520	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 44 MCG/0.5ML (24MU/ML)	6240306045D540	Brand
REBIF REBIDOSE TITRATION PACK	INTERFERON BETA-1A AUTO-INJ 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045D560	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 22 MCG/0.5ML (12MU/ML)	6240306045E520	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 44 MCG/0.5ML (24MU/ML)	6240306045E540	Brand
REBIF TITRATION PACK	INTERFERON BETA-1A PREF SYR 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045E560	Brand
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
GLATIRAMER ACETATE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Brand
AVONEX PEN	INTERFERON BETA-1A IM AUTO-INJECTOR KIT 30 MCG/0.5ML	6240306045F530	Brand
AVONEX	INTERFERON BETA-1A IM PREFILLED SYRINGE KIT 30 MCG/0.5ML	6240306045F830	Brand
EXTAVIA	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Generic
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (12) STARTER PACK	6240707020B720	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 0.25 MG (BASE EQUIV)	62407070200320	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 2 MG (BASE EQUIV)	62407070200340	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DR STARTER BOTTLE 231 MG	62405530006520	Brand
VUMERITY	DIROXIMEL FUMARATE CAPSULE DELAYED RELEASE 231 MG	62405530006540	Brand
BAFIERTAM	MONOMETHYL FUMARATE CAPSULE DELAYED RELEASE 95 MG	62405550006520	Brand
KESIMPTA	OFATUMUMAB SOLN AUTO-INJECTOR 20 MG/0.4ML	6240506500D520	Brand

PLEGRIDY	PEGINTERFERON BETA-1A IM SOLN PREFILLED SYR 125 MCG/0.5ML	6240307530E521	Brand
PONVORY 14-DAY STARTER PACK	PONESIMOD TAB STARTER PACK 2,3,4,5,6,7,8,9 &10 MG	6240706000B720	Brand
PONVORY	PONESIMOD TAB 20 MG	62407060000320	Brand
MAYZENT STARTER PACK	SIPONIMOD FUMARATE TAB 0.25 MG (7) STARTER PACK	6240707020B710	Brand
MAYZENT	SIPONIMOD FUMARATE TAB 1 MG (BASE EQUIV)	62407070200330	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.25 MG	62407025207220	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.5 MG	62407025207230	Brand
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 7 MG	62404070000320	Generic
TERIFLUNOMIDE	TERIFLUNOMIDE TAB 14 MG	62404070000330	Generic
GLATOPA	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 40 MG/ML	6240003010E540	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - For Brand Aubagio, trial and failure (of a minimum 4-week supply), or intolerance to generic teriflunomide

Product Name: Brand Copaxone 20mg/mL	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
COPAXONE	GLATIRAMER ACETATE SOLN PREFILLED SYRINGE 20 MG/ML	6240003010E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Trial and failure (of a minimum 4-week supply), or intolerance to generic glatiramer acetate

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PEN-INJECTOR 125 MCG/0.5ML	6240307530D520	Brand

PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK	6240307530D550	Brand
PLEGRIDY	PEGINTERFERON BETA-1A SOLN PREFILLED SYRINGE 125 MCG/0.5ML	6240307530E520	Brand
PLEGRIDY STARTER PACK	PEGINTERFERON BETA-1A SOLN PREF SYR 63 & 94 MCG/0.5ML PACK	6240307530E550	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 22 MCG/0.5ML (12MU/ML)	6240306045D520	Brand
REBIF REBIDOSE	INTERFERON BETA-1A SOLN AUTO-INJ 44 MCG/0.5ML (24MU/ML)	6240306045D540	Brand
REBIF REBIDOSE TITRATION PACK	INTERFERON BETA-1A AUTO-INJ 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045D560	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 22 MCG/0.5ML (12MU/ML)	6240306045E520	Brand
REBIF	INTERFERON BETA-1A SOLN PREF SYR 44 MCG/0.5ML (24MU/ML)	6240306045E540	Brand
REBIF TITRATION PACK	INTERFERON BETA-1A PREF SYR 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6240306045E560	Brand
EXTAVIA	INTERFERON BETA-1B FOR INJ KIT 0.3 MG	62403060506420	Brand
PLEGRIDY	PEGINTERFERON BETA-1A IM SOLN PREFILLED SYR 125 MCG/0.5ML	6240307530E521	Brand
PONVORY 14-DAY STARTER PACK	PONESIMOD TAB STARTER PACK 2,3,4,5,6,7,8,9 &10 MG	6240706000B720	Brand
PONVORY	PONESIMOD TAB 20 MG	62407060000320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

2.1.2 Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

OR

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

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Kesimpta (ofatumumab)
- Mayzent (siponimod)
- Vumerity (diroximel fumarate)
- Zeposia (ozanimod)

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

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

Product Name	Generic Name	GPI	Brand/Generic
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.25 MG	62407025207220	Brand
TASCENSO ODT	FINGOLIMOD LAURYL SULFATE TABLET DISINTEGRATING 0.5 MG	62407025207230	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - Patient is 10 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 18 years of age or older

AND

3.1.2 One of the following:

3.1.2.1 Both of the following:

3.1.2.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

3.1.2.1.2 Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

OR

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

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Kesimpta (ofatumumab)
- Vumerity (diroximel fumarate)
- Mayzent (siponimod)
- Zeposia (ozanimod)

OR

3.2 Both of the following:

3.2.1 Patient is younger than 18 years of age

AND

3.2.2 One of the following:

3.2.2.1 All of the following:

3.2.2.1.1 Patient weighs greater than or equal to 40kg

AND

3.2.2.1.2 Submission of medical records (e.g., chart notes) confirming lack of adequate clinical response (with related symptoms) with generic fingolimod

AND

3.2.2.1.3 Submission of medical records confirming generic fingolimod has not been effective AND valid clinical justification provided explaining how the Tascenso ODT is expected to provide benefit when generic fingolimod has not been shown to be effective despite having the same active ingredient

OR

3.2.2.2 All of the following:

3.2.2.2.1 Patient weighs les than 40kg

AND

3.2.2.2.2 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to Gilenya 0.25mg (fingolimod)

AND

3.2.2.2.3 Submission of medical records confirming generic fingolimod has not been effective AND valid clinical justification provided explaining how the Tascenso ODT is expected to provide benefit when Gilenya 0.25mg (fingolimod) has not been shown to be effective despite having the same active ingredient

AND

4 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Patient is unable to take oral tablets

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

Product Name	Generic Name	GPI	Brand/Generic
BRIUMVI	UBLITUXIMAB-XIIY SOLN FOR IV INFUSION 150 MG/6ML	62405085052030	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

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

Product Name	Generic Name	GPI	Brand/Generic
BRIUMVI	UBLITUXIMAB-XIIY SOLN FOR IV INFUSION 150 MG/6ML	62405085052030	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Lemtrada	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LEMTRADA	ALEMTUZUMAB IV INJ 12 MG/1.2ML (10 MG/ML)	62405010002020	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with alemtuzumab

AND

2.1.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 Both of the following: [E]

2.2.1 Patient has previously received treatment with alemtuzumab

AND

2.2.2 At least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Mavenclad	
Approval Length	2 Month(s) [H]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (4 TABS)	6240101500B718	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (5 TABS)	6240101500B722	Brand

MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (6 TABS)	6240101500B726	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (7 TABS)	6240101500B732	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (8 TABS)	6240101500B736	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (9 TABS)	6240101500B740	Brand
MAVENCLAD	CLADRIBINE TAB THERAPY PACK 10 MG (10 TABS)	6240101500B744	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with cladribine

AND

2.1.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 Both of the following:

2.2.1 Patient has previously received treatment with cladribine

AND

2.2.2 Patient has not already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
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 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
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 [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
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 [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
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 [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. According to the National MS Society, of the four disease courses that have been identified in MS, relapsing-remitting MS (RRMS) is characterized primarily by relapses, and secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. These two constitute “relapsing forms of MS” if they describe a disease course that is characterized by the occurrence of relapses. [7] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [6]
B. Initiation of treatment with an interferon beta medication or glatiramer acetate should be considered as soon as possible following a definite diagnosis of MS with active, relapsing disease, and may also be considered for selected patients with a first attack who are at high risk of MS. [6]

C. Based on several years of experience with glatiramer acetate and interferon beta 1a and 1b, it is the consensus of researchers and clinicians with expertise in MS that these agents are likely to reduce future disease activity and improve quality of life for many individuals with relapsing forms of MS, including those with secondary progressive disease who continue to have relapses. For those who are appropriate candidates for one of these drugs, treatment must be sustained for years. Cessation of treatment may result in a resumption of pre-treatment disease activity. [6]
D. MS specialists will use Copaxone in relapsing forms of disease, including SPMS with relapses. While there have been no trials of Copaxone in SPMS (so we have no evidenced-based data upon which to make decisions or recommendations), it's clear that where there are relapses, the injectable therapies are partially effective – they reduce relapses and new lesions on MRI. In SPMS, the trials suggest that the interferons work better in earlier, more inflammatory (i.e. those with relapses prior to the trial and with gadolinium-enhancing lesions, which is the MRI equivalent of active inflammation). Since Copaxone and the interferons appear to have rather similar efficacy in the head-to-head trials, most assume that Copaxone has a similar efficacy in SPMS: where there are relapses or active inflammation on MRI, it will likely have some benefit. Thus, most MS specialists will use Copaxone in patients with SPMS who have persistent relapses. [8]
E. According to Prescribing Information, the recommended dosage of Lemtrada is 12 mg/day administered by intravenous infusion for 2 treatment courses (first treatment course: 12 mg/day on 5 consecutive days; second treatment course: 12 mg/day on 3 consecutive days administered 12 months after the first treatment course). Following the second treatment course, subsequent treatment courses of 12 mg per day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment courses. [11]
F. Not to exceed the FDA-recommended dosage of 2 treatment courses (with the second course administered 43 weeks following the last dose of the first course). According to Prescribing Information, the recommended cumulative dosage of Mavenclad is 3.5 mg per kg body weight administered orally and divided into 2 yearly treatment courses (1.75 mg per kg per treatment course). Each treatment course is divided into 2 treatment cycles with the second cycle of each course administered 23 to 27 days after the last dose of the first cycle. Following the administration of 2 treatment courses, do not administer additional Mavenclad treatment during the next 2 years. Treatment during these 2 years may further increase the risk of malignancy. The safety and efficacy of reinitiating Mavenclad more than 2 years after completing 2 treatment courses has not been studied. [16]
G. The advantage of using combination disease-modifying therapy (DMT) compared to monotherapy DMT use has not been demonstrated, but there are safety concerns, such as reduced efficacy or disease aggravation, with combination use. [22, 23]
H. Due to the unique dosing regimen of Mavenclad, a two-month PA approval length is implemented to ensure medication for the second cycle of the same treatment course is accessible to patients before the auth expires. [16]

4 . References

1. Avonex Prescribing Information. Biogen Inc. Cambridge, MA. July 2023.
2. Betaseron Prescribing Information. Bayer. Whippany, NJ. July 2023.

3. Copaxone Prescribing Information. Teva Pharmaceuticals. North Wales, PA. November 2023.
4. Extavia Prescribing Information. Novartis. East Hanover, NJ. July 2023.
5. Rebif Prescribing Information. Serono Inc. Rockland, MA. July 2023..
6. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.
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9. Plegridy Prescribing Information. Biogen Idec Inc. Cambridge, MA. July 2023.
10. Aubagio Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2023.
11. Lemtrada Prescribing Information. Genzyme Corporation. Cambridge, MA. February 2024.
12. Glatopa Prescribing Information. Sandoz Inc. Princeton, NJ. November 2023.
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15. Mayzent Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2024.
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17. Vumerity Prescribing Information. Biogen Inc. Cambridge, MA. December 2023.
18. Bafiertam Prescribing Information. Banner Life Sciences. High Point, NC. December 2023.
19. Kesimpta Prescribing Information. Novartis Pharmaceuticals Corporation. East NJ. April 2024.
20. Hauser S, Bar-Or A, Cohen J et al. Ofatumumab versus Teriflunomide in Multiple Sclerosis. New England Journal of Medicine. 2020;383(6):546-557.
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22. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. Mayo Clinic Proceedings, 89(2), 225-240.
23. Sorensen, P., Lycke, J., Erälinna, J., Edland, A., Wu, X., & Frederiksen, J. et al. (2011). Simvastatin as add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (SIMCOMBIN study): a placebo-controlled randomised phase 4 trial. The Lancet Neurology, 10(8), 691-701.
24. Tascenso ODT Prescribing Information. Cycle Pharmaceuticals Ltd. Cambridge, United Kingdom. December 2022.
25. Briumvi Prescribing Information. TG Therapeutics, Inc. Morrisville, NC. December 2022.

Prior Authorization Guideline

Guideline ID	GL-160896
Guideline Name	Myalept (metreleptin for injection)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Myalept (metreleptin for injection)
Congenital or acquired generalized lipodystrophy Indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy

2 . Criteria

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

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
MYALEPT	METRELEPTIN FOR SUBCUTANEOUS INJ 11.3 MG	30906050002120	Brand

Approval Criteria

1 - Diagnosis of congenital or acquired generalized lipodystrophy

AND

2 - Patient is refractory to current standards of care for lipid and diabetic management

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Documentation demonstrates that patient has at least one of the following metabolic abnormalities: [2]

- Insulin resistance (defined as requiring more than 200 units per day)
- Hypertriglyceridemia
- Diabetes mellitus

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

Product Name	Generic Name	GPI	Brand/Generic
MYALEPT	METRELEPTIN FOR SUBCUTANEOUS INJ 11.3 MG	30906050002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy, such as one of the following:

- Sustained reduction in hemoglobin A1c level from baseline
- Sustained reduction in triglyceride levels from baseline

3 . References

1. Myalept Prescribing Information. Amryt Pharmaceuticals DAC. Dublin, Ireland. March 2023.
2. Handelsman Y, Oral EA, Bloomgarden ZT, et al. The clinical approach to the detection of lipodystrophy – an AACE consensus statement. Endocrine Practice 2013;19(1):107-116.
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4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160897
Guideline Name	Ninlaro (ixazomib citrate)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ninlaro (ixazomib citrate)
Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. Limitations of Use: NINLARO is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials

2 . Criteria

Product Name: Ninlaro	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NINLARO	IXAZOMIB CITRATE CAP 2.3 MG (BASE EQUIVALENT)	21536045100120	Brand
NINLARO	IXAZOMIB CITRATE CAP 3 MG (BASE EQUIVALENT)	21536045100130	Brand
NINLARO	IXAZOMIB CITRATE CAP 4 MG (BASE EQUIVALENT)	21536045100140	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

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

Product Name	Generic Name	GPI	Brand/Generic
NINLARO	IXAZOMIB CITRATE CAP 2.3 MG (BASE EQUIVALENT)	21536045100120	Brand
NINLARO	IXAZOMIB CITRATE CAP 3 MG (BASE EQUIVALENT)	21536045100130	Brand
NINLARO	IXAZOMIB CITRATE CAP 4 MG (BASE EQUIVALENT)	21536045100140	Brand

Approval Criteria

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

3 . References

1. Ninlaro Prescribing Information. Takeda Pharmaceutical Company Limited. Cambridge, MA. November 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed 12 February, 2024

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160898
Guideline Name	Nityr and Orfadin
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 administered using an oral syringe. If patients can swallow semi-solid foods, the tablets can also be crushed and mixed with applesauce. For preparation and administration instructions, see the full prescribing information [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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160899
Guideline Name	Non-Formulary & Excluded Drug Exceptions Process for Drugs of Clinical Concern
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 (stiripentol)*, Epidiolex (cannabidiol)*, lamotrigine, topiramate, zonisamide, levetiracetam, Briviact (brivaracetam)***
Anticonvulsants	Oxtellar XR (oxcarbazepine extended-release)	• **Generic oxcarbazepine**
Anticonvulsants	Aptiom (eslicarbazepine)	• **Generic oxcarbazepine tablets**
Anticonvulsants	Zonisade (zonisamide oral suspension)	• **Generic zonisamide capsule**
Anticonvulsants	Brand Vimpat (lacosamide)	• **Generic lacosamide**
Anticonvulsants	Elepsia XR (levetiracetam ER)	• **generic levetiracetam 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 XL 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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160900
Guideline Name	Non-formulary Descovy and Truvada
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160901
Guideline Name	Non-steroidal Anti-Inflammatory Agents - PA, ST
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Cambia (diclofenac) powder
Migraine Indicated for the acute treatment of migraine attacks with or without aura in adults (18 years of age or older). Limitations of use: Cambia is not indicated for the prophylactic therapy of migraine. The safety and effectiveness of Cambia have not been established for cluster headache, which is present in an older, predominantly male population.
Drug Name: Celebrex (celecoxib)
Multiple Indicated for: 1) Osteoarthritis (OA) 2) Rheumatoid Arthritis (RA) 3) Juvenile Rheumatoid Arthritis (JRA) in patients 2 years of age or older 4) Ankylosing Spondylitis (AS) 5) Acute Pain 6) Primary Dysmenorrhea
Drug Name: Sprix (ketorolac tromethamine) nasal spray
Moderate to moderately severe pain Indicated in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the

opioid level. Limitations of Use: Sprix is not for use in pediatric patients less than 2 years of age.
Drug Name: Tivorbex (indomethacin) capsules
Mild to moderate pain Indicated for treatment of mild to moderate acute pain in adults.
Drug Name: Pennsaid (diclofenac sodium) topical solution
Osteoarthritis (OA) Indicated for the treatment of the pain of osteoarthritis of the knee(s).
Drug Name: Indocin
Multiple Indications Indicated for the treatment for the following: moderate to severe rheumatoid arthritis including acute flare of chronic disease, moderate to severe ankylosing spondylitis, moderate to severe osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) or acute gouty arthritis.
Drug Name: Vivlodex
Osteoarthritis (OA) Indicated for the treatment of osteoarthritis (OA) pain.
Drug Name: Zorvolex (diclofenac)
Pain Indicated for the treatment of mild to moderate acute pain and management of osteoarthritis (OA) pain.
Drug Name: Lofena
Primary dysmenorrhea, mild to moderate pain, osteoarthritis, and rheumatoid arthritis Indicated for treatment of primary dysmenorrhea, for relief of mild to moderate pain, for relief of the signs and symptoms of osteoarthritis, for the relief of the signs and symptoms of rheumatoid arthritis.
Drug Name: Meloxicam oral suspension 7.5mg/5mL
Multiple Indicated for: 1) Osteoarthritis (OA) 2) Rheumatoid Arthritis (RA) 3) Juvenile Rheumatoid Arthritis (JRA) in patients 2 years of age or older
Drug Name: Zipsor (diclofenac potassium)
Mild to moderate acute pain Indicated for relief of mild to moderate acute pain in adult and pediatric patients 12 years of age and older.
Drug Name: Indomethacin Suspension 25mg/5ml
Multiple Indications Indicated for the treatment for the following: moderate to severe rheumatoid arthritis including acute flare of chronic disease, moderate to severe ankylosing

spondylitis, moderate to severe osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) or acute gouty arthritis.

Drug Name: Tolectin (tolmetin)

Multiple Indications Indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis. TOLECTIN tablets are indicated in the treatment of acute flares and the long-term management of the chronic disease. Indicated for treatment of juvenile rheumatoid arthritis. The safety and effectiveness of TOLECTIN tablets have not been established in pediatric patients under 2 years of age.

2 . Criteria

Product Name: Sprix nasal spray, Brand Ketorolac nasal spray	
Approval Length	5 Days [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPRIX	KETOROLAC TROMETHAMINE NASAL SPRAY 15.75 MG/SPRAY	66100037102090	Brand
KETOROLAC TROMETHAMINE	KETOROLAC TROMETHAMINE NASAL SPRAY 15.75 MG/SPRAY	66100037102090	Generic

Approval Criteria

1 - Diagnosis of moderate to moderately severe pain

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to oral ketorolac* tablets

OR

2.2 Patient is unable to take medications orally

Notes	*Ketorolac is recommended only for patients less than 65 years old. [B, C]

Product Name: Brand Pennsaid topical solution, Generic diclofenac topical solution	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PENNSAID	DICLOFENAC SODIUM SOLN 2%	90210030302030	Brand
DICLOFENAC SODIUM	DICLOFENAC SODIUM SOLN 1.5%	90210030302025	Generic
DICLOFENAC SODIUM	DICLOFENAC SODIUM SOLN 2%	90210030302030	Generic

Approval Criteria

1 - Diagnosis of osteoarthritis of the knee(s)

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to at least two prescription strength oral NSAIDs (e.g., diclofenac, diclofenac ER, ibuprofen, indomethacin, etc.)

OR

2.2 Documented swallowing disorder

OR

2.3 History of peptic ulcer disease/gastrointestinal bleed

OR

2.4 Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g., use of anticoagulants, chronic corticosteroids)

AND

3 - Trial and failure, contraindication, or intolerance to both of the following: (applies to Brand Pennsaid only)

- generic topical diclofenac 1.5% solution
- generic topical diclofenac 2% solution

Product Name: Brand Pennsaid topical solution, Generic diclofenac topical solution	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DICLOFENAC SODIUM	DICLOFENAC SODIUM SOLN 1.5%	90210030302025	Generic
PENNSAID	DICLOFENAC SODIUM SOLN 2%	90210030302030	Brand
DICLOFENAC SODIUM	DICLOFENAC SODIUM SOLN 2%	90210030302030	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response (e.g., improvement in pain symptoms of osteoarthritis) to therapy

Product Name: Tivorbex*, Brand Diclofenac 50mg, Brand Indomethacin 20mg*, Cambia**^, Brand Celebrex, Indocin*, Lofena, Vivlodex, Zorvolex, Brand diclofenac 35mg capsule, Meloxicam oral suspension 7.5mg/5mL, Brand Zipsor, generic diclofenac 25mg capsule, Generic Indomethacin Suspension 25mg/5ml*, Tolectin

Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TIVORBEX	INDOMETHACIN CAP 20 MG	66100030000104	Brand
TIVORBEX	INDOMETHACIN CAP 40 MG	66100030000107	Brand
CAMBIA	DICLOFENAC POTASSIUM PACKET 50 MG	67600040103020	Brand
VIVLODEX	MELOXICAM CAP 5 MG	66100052000115	Brand
VIVLODEX	MELOXICAM CAP 10 MG	66100052000125	Brand
ZORVOLEX	DICLOFENAC CAP 18 MG	66100007000120	Brand
ZORVOLEX	DICLOFENAC CAP 35 MG	66100007000130	Brand
INDOCIN	INDOMETHACIN SUSP 25 MG/5ML	66100030001805	Brand
INDOCIN	INDOMETHACIN SUPPOS 50 MG	66100030005205	Brand
INDOMETHACIN CAP 20 MG	INDOMETHACIN CAP 20 MG	66100030000104	Brand
DICLOFENAC	DICLOFENAC CAP 35 MG	66100007000130	Generic
LOFENA	DICLOFENAC POTASSIUM TAB 25 MG	66100007100320	Brand
MELOXICAM	MELOXICAM SUSP 7.5 MG/5ML	66100052001820	Generic
DICLOFENAC POTASSIUM	DICLOFENAC POTASSIUM CAP 25 MG	66100007100120	Generic
ZIPSOR	DICLOFENAC POTASSIUM CAP 25 MG	66100007100120	Brand
CELEBREX	CELECOXIB CAP 50 MG	66100525000110	Brand
CELEBREX	CELECOXIB CAP 100 MG	66100525000120	Brand
CELEBREX	CELECOXIB CAP 200 MG	66100525000130	Brand
CELEBREX	CELECOXIB CAP 400 MG	66100525000140	Brand
DICLOFENAC POTASSIUM	DICLOFENAC POTASSIUM (MIGRAINE) PACKET 50 MG	67600040103020	Generic
INDOMETHACIN	INDOMETHACIN SUSP 25 MG/5ML	66100030001805	Generic
TOLECTIN 600	TOLMETIN SODIUM TAB 600 MG	66100090100320	Brand

Approval Criteria

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

• diclofenac potassium tab or diclofenac sodium • diflunisal • etodolac • fenoprofen • flurbiprofen • ibuprofen • indomethacin • ketoprofen • ketorolac • meclofenamate • meloxicam • nabumetone • naproxen • oxaprozin • piroxicam • sulindac • tolmetin • celecoxib	
Notes	*Per the American Geriatrics Society 2023 updated Beers criteria, ind omethacin is not recommended for patients greater than or equal to 6 5 years old [B] **Per the American Geriatrics Society 2023 updated B eers criteria, chronic use of NSAIDs, including diclofenac, is not reco mmended for patients greater than or equal to 65 years old unless oth er alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol) [B] ^Product may be excluded depending on the plan.

3 . Endnotes

A. The total duration of use of Sprix alone or sequentially with other formulations of ketorolac (IM/IV or oral) must not exceed 5 days because of the potential for increasing the frequency and severity of adverse reactions associated with the recommended doses. Treat patients for the shortest duration possible, and do not exceed 5 days of therapy with Sprix. [1]
B. This drug is included on the 2023 Beers Criteria for Potentially Inappropriate Medication Use in Older Adults greater than or equal to 65 years old. [3]
C. This drug is included on the 2013 Health Plan Employer Data and Information Set (HEDIS) list of high-risk medications in the elderly (greater than or equal to 65 years old) [4]

4 . References

1. Sprix prescribing information. Zyla Life Sciences US Inc. Wayne, PA. July 2023.
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5. Tivorbex prescribing information. Iroko Pharmaceuticals LLC, Philadelphia, PA. January 2020.
6. Cambia prescribing information. Depomed, Inc, Newark, CA. October 2019.
7. Vivlodex prescribing information. Egalet US Inc. Wayne PA. April 2021.
8. Indocin prescribing information. Iroko Pharmaceuticals, LLC. Philadelphia, PA. October 2018.
9. Zorvolex prescribing information. Zyla Life Sciences US Inc. Wayne, PA. April 2021.
10. Lofena Prescribing Information. Carwin Pharmaceutical Associates, LLC. Hazlet, NJ. July 2021.
11. Diclofenac Sodium Solution Prescribing Information. Apotex Corporation. Weston, FL. April 2022.
12. Meloxicam Oral Suspension Prescribing Information. Avondale Pharmaceuticals, LLC. Birmingham, AL. January 2024.
13. Indomethacin Suspension Prescribing Information. ANI Pharmaceuticals Inc, Baudette, MN 56623. January 2024.
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5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160902
Guideline Name	Nucala (mepolizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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) [F, 7]

AND

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

- Pulmonologist
- Rheumatologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increase in remission time)

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand

Approval Criteria

1 - Diagnosis of hypereosinophilic syndrome (HES)

AND

2 - Patient is 12 years of age or older

AND

3 - Patient has been diagnosed for at least 6 months

AND

4 - Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

AND

5 - Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative

AND

6 - Patient has uncontrolled HES defined as both of the following:

- History of 2 or more flares within the past 12 months [I]
- Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter

AND

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

- Corticosteroid therapy (e.g., prednisone)
- Cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib)

AND

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

- Allergist/Immunologist
- Hematologist

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)

Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
NUCALA	MEPOLIZUMAB FOR INJ 100 MG	44604055002120	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML	4460405500D530	Brand
NUCALA	MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF SYRINGE 100 MG/ML	4460405500E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose)

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [5]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320

Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [5]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Beclometasone dipropionate (pMDI, extrafine particle, HFA)	50-100	> 100-200	> 200
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Budesonide (nebules)	250-500	>500-1000	>1000

Ciclesonide (pMDI, extrafine particle*, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50		n.a.
Fluticasone propionate (DPI)	50-100	> 100-200	> 200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	> 100-200	> 200
Mometasone furoate (pMDI, standard particle, HFA)	100		200

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. Patients included across the 3 pivotal studies (DREAM, MENSA, and SIRIUS) [2-4] were characterized with clinical features of severe refractory asthma per American Thoracic Society (ATS) criteria [5]. Per the ATS: "Severe asthma is defined as asthma which requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller (and/or systemic corticosteroids) to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy.'' This definition includes patients who received an adequate trial of these therapies in whom treatment was stopped due to lack of response. In patients greater than 6 years of age, ''Gold Standard/International Guidelines treatment'' is high dose ICS plus a long-acting beta 2-agonist (LABA), leukotriene modifier or theophylline and/or continuous or near continuous systemic corticosteroids as background therapy."
B. Inclusion criteria was modified from the DREAM study to the MENSA study to be limited to patients with eosinophils greater than or equal to 150 cells/mcL in the peripheral blood

at screening or greater than or equal to 300 cells/mcL at some time during the previous year [3].

C. The primary endpoint for the DREAM and MENSA studies was the annual rate of clinically significant asthma exacerbations as a composite of the required use of systemic corticosteroids for at least 3 days, admission, or ED visit. Both studies showed mepolizumab-treated patients experienced a significant improvement in exacerbation rates compared with baseline and compared with placebo. [2, 3]
D. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [6]
E. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [6].
F. Nucala was approved for Eosinophilic Granulomatosis with Polyangiitis (EGPA) based on the results from the pivotal, 52-week, Phase III MIRRA study. MIRRA looked at the efficacy and safety of 300 mg of mepolizumab administered SQ every four weeks versus placebo as add-on therapy to standard of care (corticosteroids plus or minus immunosuppressants) in 136 patients with relapsing and/or refractory EGPA. MIRRA reported statistically significant outcomes with both co-primary endpoints (i.e., accrued time in remission and proportion of patients achieving remission) in favor of the treatment group [7, 8].
G. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [6]
H. Per P&T Committee, February 2019, revised exacerbation requirement to mirror other IL-5 antagonists.
I. Historical flares were defined as a worsening of HES-related clinical symptoms or a blood eosinophil count requiring an escalation in therapy. [1]
J. Other agents used for CRSwNP include intranasal corticosteroids and nasal saline.

5 . References

1. Nucala prescribing information. GlaxoSmithKline LLC. Philadelphia, PA. March 2023.
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7. GlaxoSmithKline Press Release. GSK achieves approval for Nucala (mepolizumab) for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) for adults in the US. Website. Available from: https://www.gsk.com/en-gb/media/press-releases/gsk-achieves-approval-for-nucala-mepolizumab-for-the-treatment-of-eosinophilic-granulomatosis-with-polyangiitis-egpa-for-adults-in-the-us/. Accessed March 11, 2021.
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6 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160903
Guideline Name	Octreotide Products - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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, Sandostatin 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
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 - 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 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

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin 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

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 - 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 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic octreotide

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 - 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 patient has responded to and tolerated treatment with generic octreotide or lanreotide

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin 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

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 only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (applies to Brand Sandostatin only)

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin 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

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 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic octreotide

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin 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

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, 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

Approval Criteria

1 - Documentation of 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

Approval Criteria

1 - Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic octreotide

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160904
Guideline Name	Ogsiveo (nirogacestat)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ogsiveo (nirogacestat)
Desmoid Tumor Indicated for adult patients with progressing desmoid tumors who require systemic treatment.

2 . Criteria

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

Product Name	Generic Name	GPI	Brand/Generic
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 50 MG	21532350200320	Brand
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 100 MG	21532350200330	Brand
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 150 MG	21532350200340	Brand

Approval Criteria

1 - Diagnosis of desmoid tumor

AND

2 - Disease is progressive

AND

3 - Patient requires systemic treatment

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

Product Name	Generic Name	GPI	Brand/Generic
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 50 MG	21532350200320	Brand
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 100 MG	21532350200330	Brand
OGSIVEO	NIROGACESTAT HYDROBROMIDE TAB 150 MG	21532350200340	Brand

Approval Criteria

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

3 . References

1. Ogsiveo Prescribing Information. SpringWorks Therapeutics, Inc. Stamford, CT. April 2024.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160905
Guideline Name	Omega-3-Acid Derivatives
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160906
Guideline Name	Onpattro (patisiran) & Tegsedi (inotersen)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 - Patient has a transthyretin (TTR) mutation (e.g., V30M) [1-4]

AND

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

- Patient has a baseline polyneuropathy disability (PND) score ≤ 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 has demonstrated a benefit from 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 ≤ 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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160907
Guideline Name	Onureg (azacitidine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-158854
Guideline Name	Ophthalmic Antihistamines
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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.

Prior Authorization Guideline

Guideline ID	GL-160908
Guideline Name	Opioid Quantity Limit Overrides
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160909
Guideline Name	Opioid Risk Management
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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

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	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-	65991303050115	Generic

	DIHYDROCODEINE CAP 320.5-30-16 MG		
HYDROCODONE/IBUPROFEN	HYDROCODONE-IBUPROFEN TAB 7.5-200 MG	65991702500320	Generic
ULTRAM	TRAMADOL HCL TAB 50 MG	65100095100320	Brand
TRAMADOL HCL	TRAMADOL HCL TAB 50 MG	65100095100320	Generic
TRAMADOL HYDROCHLORIDE/ACETAMINOPHEN	TRAMADOL-ACETAMINOPHEN TAB 37.5-325 MG	65995002200320	Generic
ULTRACET	TRAMADOL-ACETAMINOPHEN TAB 37.5-325 MG	65995002200320	Brand
BUTORPHANOL TARTRATE	BUTORPHANOL TARTRATE NASAL SOLN 10 MG/ML	65200020102050	Generic
NALOCET	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	65990002200303	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 15 MG	6510007510A540	Brand
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 30 MG	6510007510A560	Brand
OXYCODONE/ASPIRIN	OXYCODONE-ASPIRIN TAB 4.8355-325 MG	65990002220340	Generic
TUXARIN ER	CODEINE PHOS-CHLORPHENIRAMINE MALEATE TAB ER 12HR 54.3-8 MG	43995202327430	Brand
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG	65990002020310	Brand
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG	65990002020310	Brand
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 6.12-325 MG	65990002020320	Brand
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 6.12-325 MG	65990002020320	Brand
BENZHYDROCODONE/ACETAMINOPHEN	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 8.16-325 MG	65990002020330	Brand
APADAZ	BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 8.16-325 MG	65990002020330	Brand

TRAMADOL HYDROCHLORIDE	TRAMADOL HCL TAB 100 MG	65100095100340	Generic
OXYCODONE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	65990002200303	Generic
ROXYBOND	OXYCODONE HCL TAB ABUSE DETER 5 MG	6510007510A530	Brand
PROLATE	OXYCODONE W/ ACETAMINOPHEN SOLN 10-300 MG/5ML	65990002202020	Generic
OXYCODONE HYDROCHLORIDE/ACETAMINOPHEN	OXYCODONE W/ ACETAMINOPHEN SOLN 10-300 MG/5ML	65990002202020	Generic
HYCET	HYDROCODONE-ACETAMINOPHEN SOLN 7.5-325 MG/15ML	65991702102015	Brand
HYDROCODONE BITARTRATE/ACETAMINOPHEN	HYDROCODONE-ACETAMINOPHEN SOLN 7.5-325 MG/15ML	65991702102015	Generic
HYDROCODONE/ACETAMINOPHEN	HYDROCODONE/ACETAMINOPHEN TAB 10-325MG	65991702100305	Generic
TRAMADOL HYDROCHLORIDE	TRAMADOL HCL TAB 25 MG	65100095100310	Generic

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	65990002220 3	
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

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	65990002202020	Generic

	SOLN 10-300 MG/5ML		
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 POLIST ER 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 authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Long Acting Opioids: 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 MME 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 criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER, generic hydromorphone ER

Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 9 MG	6510007500A310	Brand

XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 13.5 MG	6510007500A315	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 18 MG	6510007500A320	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 27 MG	6510007500A330	Brand
XTAMPZA ER	OXYCODONE CAP ER 12HR ABUSE-DETERRENT 36 MG	6510007500A340	Brand
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 15 MG	65100055100415	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 30 MG	65100055100432	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 30 MG	65100055100432	Brand
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 60 MG	65100055100445	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Brand
MORPHINE SULFATE CR	MORPHINE SULFATE TAB ER 100 MG	65100055100460	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE TAB ER 200 MG	65100055100480	Generic
MS CONTIN	MORPHINE SULFATE TAB ER 200 MG	65100055100480	Brand
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 5 MG	65100080107405	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 7.5 MG	65100080107407	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 10 MG	65100080107410	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 15 MG	65100080107415	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 20 MG	65100080107420	Generic

OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 30 MG	65100080107430	Generic
OXYMORPHONE HYDROCHLORIDE ER	OXYMORPHONE HCL TAB ER 12HR 40 MG	65100080107440	Generic
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG	6510003010A810	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG	6510003010A820	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG	6510003010A830	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG	6510003010A840	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG	6510003010A850	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG	6510003010A860	Brand
HYSINGLA ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG	6510003010A870	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 10 MG	6510007510A710	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 10 MG	6510007510A710	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 15 MG	6510007510A715	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 15 MG	6510007510A715	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 20 MG	6510007510A720	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 20 MG	6510007510A720	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 30 MG	6510007510A730	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 30 MG	6510007510A730	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 40 MG	6510007510A740	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 40 MG	6510007510A740	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 60 MG	6510007510A760	Generic
OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 60 MG	6510007510A760	Brand
OXYCODONE HCL ER	OXYCODONE HCL TAB ER 12HR DETER 80 MG	6510007510A780	Generic

OXYCONTIN	OXYCODONE HCL TAB ER 12HR DETER 80 MG	6510007510A780	Brand
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 30 MG	65100055207020	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 45 MG	65100055207025	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 60 MG	65100055207030	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 75 MG	65100055207035	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 90 MG	65100055207040	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE BEADS CAP ER 24HR 120 MG	65100055207050	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 8 MG	65100035107521	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 12 MG	65100035107531	Generic
HYDROMORPHONE HCL ER	HYDROMORPHONE HCL TAB ER 24HR 16 MG	65100035107541	Generic
HYDROMORPHONE HYDROCHLORIDE ER	HYDROMORPHONE HCL TAB ER 24HR 32 MG	65100035107556	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG	6510003010A810	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG	6510003010A820	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG	6510003010A830	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG	6510003010A840	
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG	6510003010A850	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG	6510003010A860	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG	6510003010A870	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 10 MG	65100055107010	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 20 MG	65100055107020	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 30 MG	65100055107030	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 50 MG	65100055107040	Generic

MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 60 MG	65100055107045	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 80 MG	65100055107050	Generic
MORPHINE SULFATE ER	MORPHINE SULFATE CAP ER 24HR 100 MG	65100055107060	Generic
METHADONE HCL	METHADONE HCL TAB 5 MG	65100050100305	Generic
METHADONE HYDROCHLORIDE	METHADONE HCL TAB 5 MG	65100050100305	Generic
METHADONE HCL	METHADONE HYDROCHLORIDE	65100050100310	Generic
METHADONE HYDROCHLORIDE	METHADONE HYDROCHLORIDE	65100050100310	Generic
FENTANYL	FENTANYL TD PATCH 72HR 25 MCG/HR	65100025008620	
FENTANYL	FENTANYL TD PATCH 72HR 50 MCG/HR	65100025008630	
FENTANYL	FENTANYL TD PATCH 72HR 75 MCG/HR	65100025008640	
FENTANYL	FENTANYL TD PATCH 72HR 100 MCG/HR	65100025008650	
FENTANYL	FENTANYL TD PATCH 72HR 12 MCG/HR	65100025008610	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 10 MG	65100030106910	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 15 MG	65100030106915	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 20 MG	65100030106920	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 30 MG	65100030106930	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 40 MG	65100030106940	Generic
HYDROCODONE BITARTRATE ER	HYDROCODONE BITARTRATE CAP ER 12HR 50 MG	65100030106950	Generic

Approval Criteria

1 - One of the following:

1.1 Diagnosis of cancer

OR

1.2 Patient is receiving opioids as part of end-of-life care

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Brand
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Generic

BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Generic

Approval Criteria

1 - Patient is being treated for cancer related pain or pain associated with end-of-life

Notes	*Prior authorization may not apply depending on the plan

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
Diagnosis	Non- Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Brand

BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Generic

Approval Criteria

1 - The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For opioid dependence

AND

3 - The patient is not receiving other long-acting opioids concurrently

Notes	*Prior authorization may not apply depending on the plan. If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
Diagnosis	Non-Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Brand
BELBUCA	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Brand

BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR	65200010008820	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 7.5 MCG/HR	65200010008825	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 10 MCG/HR	65200010008830	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 15 MCG/HR	65200010008835	Generic
BUTRANS	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE	BUPRENORPHINE TD PATCH WEEKLY 20 MCG/HR	65200010008840	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 75 MCG (BASE EQUIVALENT)	65200010108210	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 150 MCG (BASE EQUIVALENT)	65200010108220	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 300 MCG (BASE EQUIVALENT)	65200010108230	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 450 MCG (BASE EQUIVALENT)	65200010108240	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 600 MCG (BASE EQUIVALENT)	65200010108250	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 750 MCG (BASE EQUIVALENT)	65200010108260	Generic
BUPRENORPHINE BUCCAL	BUPRENORPHINE HCL BUCCAL FILM 900 MCG (BASE EQUIVALENT)	65200010108270	Generic

Approval Criteria

1 - Documentation has been provided addressing ALL of the following

- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention
- Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory)

• Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10) • Rationale for not tapering and discontinuing opioid • Patient has been screened for comorbid mental health conditions • If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP • If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose	
Notes	*Prior authorization may not apply depending on the plan. If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

2 . References

1. Zohydro ER Prescribing Information.Currax Pharmaceuticals LLC. October 2019.

3 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160910
Guideline Name	Oral Fentanyl Products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Actiq (fentanyl citrate) oral transmucosal lozenge
Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Actiq. This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Actiq is contraindicated in the management of acute or postoperative pain. Actiq is intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Actiq Q may be dispensed only to outpatients enrolled in the program. For inpatient administration of Actiq (e.g., hospitals, hospices, and long-term care facilities that prescribe

for inpatient use), patient and prescriber enrollment is not required. Not for use in opioid non-tolerant patients. Not for use in the management of acute or postoperative pain, including headache/migraine and dental pain.

Drug Name: Fentora (fentanyl buccal tablet)

Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg/hr of transdermal fentanyl, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids while taking Fentora. This product must not be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Fentora is contraindicated in the management of acute or postoperative pain. Fentora is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Fentora may be dispensed only to outpatients enrolled in the program. For inpatient administration of Fentora (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required. Not for use in opioid non-tolerant patients. Not for use in the management of acute or postoperative pain, including headache/migraine and dental pain.

Drug Name: Lazanda (fentanyl) nasal spray

Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least: 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, 60 mg of oral hydrocodone/day, or an equianalgesic dose of another opioid for a week or longer. Patients must remain on around-the-clock opioids when taking Lazanda. Lazanda is contraindicated for patients who are not already tolerant to opioids because life-threatening respiratory depression and death could occur in patients not taking chronic opioids. For this reason, Lazanda is contraindicated in the management of acute or postoperative pain, including headache/migraine, or dental pain. Lazanda is intended to be prescribed only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Lazanda may be dispensed only to outpatients enrolled in the program.For inpatient administration of Lazanda (e.g., hospitals, hospices, and long-term care facilities that prescribefor inpatient use), patient enrollment is not required. Not for use in opioid non-tolerant patients. Not for use in the management of acute or postoperative pain, including headache/migraine and dental pain.

Drug Name: Subsys (fentanyl sublingual spray)

Breakthrough pain Indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Subsys . This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Subsys is contraindicated in the management of acute or postoperative pain. Subsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use As part of the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS Program, Subsys may be dispensed only to outpatients enrolled in the program. For inpatient administration (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use) of Subsys, patient enrollment is not required. Not for use in opioid non-tolerant patients. Not for use in the management of acute or postoperative pain, including headache/migraine and dental pain.

2 . Criteria

Product Name: Brand Actiq, Fentora*, Generic fentanyl citrate*, Lazanda*, or Subsys	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 200 MCG	65100025108450	Brand
ACTIQ	FENTANYL CITRATE LOLLIPOP 400 MCG	65100025108455	Brand
ACTIQ	FENTANYL CITRATE LOLLIPOP 600 MCG	65100025108460	Brand
ACTIQ	FENTANYL CITRATE LOLLIPOP 800 MCG	65100025108465	Brand
ACTIQ	FENTANYL CITRATE LOLLIPOP 1200 MCG	65100025108475	Brand
ACTIQ	FENTANYL CITRATE LOLLIPOP 1600 MCG	65100025108485	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 100 MCG (BASE EQUIV)	65100025100310	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 200 MCG (BASE EQUIV)	65100025100320	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 400 MCG (BASE EQUIV)	65100025100330	Brand

FENTORA	FENTANYL CITRATE BUCCAL TAB 600 MCG (BASE EQUIV)	65100025100340	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 800 MCG (BASE EQUIV)	65100025100350	Brand
LAZANDA	FENTANYL CITRATE NASAL SPRAY 100 MCG/ACT (BASE EQUIV)	65100025102050	Brand
LAZANDA	FENTANYL CITRATE NASAL SPRAY 400 MCG/ACT (BASE EQUIV)	65100025102060	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 100 MCG	65100025000910	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 200 MCG	65100025000920	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 400 MCG	65100025000930	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 600 MCG	65100025000940	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 800 MCG	65100025000950	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 1200 MCG (600 MCG X 2)	65100025000960	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 1600 MCG (800 MCG X 2)	65100025000970	Brand
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 200 MCG (BASE EQUIV)	65100025100320	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 400 MCG (BASE EQUIV)	65100025100330	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 600 MCG (BASE EQUIV)	65100025100340	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 800 MCG (BASE EQUIV)	65100025100350	Generic

Approval Criteria

1 - For the management of breakthrough cancer pain [A]

AND

2 - Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: [3, B]

- Morphine sulfate at doses of greater than or equal to 60 mg/day
- Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr
- Oxycodone at a dose of greater than or equal to 30 mg/day
- Oral hydromorphone at a dose of greater than or equal to 8 mg/day
- Oral oxymorphone at a dose of greater than or equal to 25 mg/day
- Oral hydrocodone at a dose of greater than or equal to 60mg/day

- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

3 - Trial and failure or intolerance to generic fentanyl lozenge

AND

4 - The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

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

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

Notes	*Product may be excluded depending on the plan

Product Name: Generic fentanyl lozenge	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 200 MCG	65100025108450	Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 400 MCG	65100025108455	Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 600 MCG	65100025108460	Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 800 MCG	65100025108465	Generic

FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 1200 MCG	65100025108475	Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 1600 MCG	65100025108485	Generic

Approval Criteria

1 - For the management of breakthrough cancer pain [A]

AND

2 - Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: [3, B]

- Morphine sulfate at doses of greater than or equal to 60 mg/day
- Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr
- Oxycodone at a dose of greater than or equal to 30 mg/day
- Oral hydromorphone at a dose of greater than or equal to 8 mg/day
- Oral oxymorphone at a dose of greater than or equal to 25 mg/day
- Oral hydrocodone at a dose of greater than or equal to 60mg/day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

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

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

Product Name: Brand Actiq, Fentora*, Generic fentanyl citrate*, Generic fentanyl lozenge, Lazanda*, or Subsys	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Product Name	Generic Name	GPI	Brand/Generic
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 200 MCG	65100025108450	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 200 MCG	65100025108450	Brand
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 400 MCG	65100025108455	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 400 MCG	65100025108455	Brand
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 600 MCG	65100025108460	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 600 MCG	65100025108460	Brand
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 800 MCG	65100025108465	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 800 MCG	65100025108465	Brand
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 1200 MCG	65100025108475	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 1200 MCG	65100025108475	Brand
FENTANYL CITRATE ORAL TRANSMUCOSAL	FENTANYL CITRATE LOLLIPOP 1600 MCG	65100025108485	Generic
ACTIQ	FENTANYL CITRATE LOLLIPOP 1600 MCG	65100025108485	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 100 MCG (BASE EQUIV)	65100025100310	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 200 MCG (BASE EQUIV)	65100025100320	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 400 MCG (BASE EQUIV)	65100025100330	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 600 MCG (BASE EQUIV)	65100025100340	Brand
FENTORA	FENTANYL CITRATE BUCCAL TAB 800 MCG (BASE EQUIV)	65100025100350	Brand
LAZANDA	FENTANYL CITRATE NASAL SPRAY 100 MCG/ACT (BASE EQUIV)	65100025102050	Brand
LAZANDA	FENTANYL CITRATE NASAL SPRAY 400 MCG/ACT (BASE EQUIV)	65100025102060	Brand

SUBSYS	FENTANYL SUBLINGUAL SPRAY 100 MCG	65100025000910	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 200 MCG	65100025000920	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 400 MCG	65100025000930	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 600 MCG	65100025000940	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 800 MCG	65100025000950	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 1200 MCG (600 MCG X 2)	65100025000960	Brand
SUBSYS	FENTANYL SUBLINGUAL SPRAY 1600 MCG (800 MCG X 2)	65100025000970	Brand
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 200 MCG (BASE EQUIV)	65100025100320	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 400 MCG (BASE EQUIV)	65100025100330	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 600 MCG (BASE EQUIV)	65100025100340	Generic
FENTANYL CITRATE	FENTANYL CITRATE BUCCAL TAB 800 MCG (BASE EQUIV)	65100025100350	Generic

Approval Criteria

1 - For the management of breakthrough cancer pain

AND

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

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

AND

3 - The prescriber maintains and provides chart documentation of the patient's evaluation, including all of the following: [3]

- An appropriate patient medical history and physical examination
- A description of the nature and intensity of the pain

• Documentation of appropriate dose escalation • Documentation of ongoing, periodic review of the course of opioid therapy • An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function) • Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian	
Notes	*Product may be excluded depending on the plan.

3 . Endnotes

A. Actiq, Fentora, Lazanda, and Subsys are intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain [1, 2, 4, 5]
B. Actiq, Fentora, Lazanda, and Subsys are only intended for patients who are opioid tolerant. Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily, at least 60 mg of oral hydrocodone daily, or an equianalgesic dose of another opioid for a week or longer. [1, 2, 4, 5]

4 . References

1. Actiq Prescribing Information. Cephalon. North Wales, PA. March 2021.
2. Fentora Prescribing Information. Cephalon. North Wales, PA. December 2023.
3. American Academy of Pain Medicine. The use of opioids for the treatment of chronic pain (2013). Available at: http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf. Accessed August 12, 2020.
4. Lazanda Prescribing Information. West Therapeutic Development, LLC. March 2021.
5. Subsys Prescribing Information. INSYS Therapeutics, Inc. Chandler, AZ. April 2021.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-162298
Guideline Name	Orencia (abatacept)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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-160453
Guideline Name	Orencia (abatacept)
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

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
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Orencia 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 adalimumab 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 Orencia 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: 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)
- Stelara (ustekinumab)
- Skyrizi (risankizumab-rzaa)
- Tremfya (guselkumab)
- Rinvoq/LQ (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Orencia 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 adalimumab 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

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

Prior Authorization Guideline

Guideline ID	GL-160911
Guideline Name	Orgovyx (relugolix)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Orgovyx (relugolix)
Prostate Cancer Indicated for the treatment of adult patients with advanced prostate cancer.

2 . Criteria

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

Product Name	Generic Name	GPI	Brand/Generic
ORGOVYX	RELUGOLIX TAB 120 MG	21405570000320	Brand

Approval Criteria

1 - Diagnosis of advanced prostate cancer

AND

2 - Disease is one of the following:

- Evidence of biochemical or clinical relapse following local primary intervention with curative intent
- Newly diagnosed androgen-sensitive metastatic disease
- Advanced localized disease unlikely to be cured by local primary intervention with curative intent

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

Product Name	Generic Name	GPI	Brand/Generic
ORGOVYX	RELUGOLIX TAB 120 MG	21405570000320	Brand

Approval Criteria

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

AND

2 - Documentation of serum testosterone level less than 50 ng/dL

3 . References

1. Orgovyx Prescribing Information. Myovant Sciences, Inc. Brisbane, CA. August 2023.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160912
Guideline Name	Orkambi (lumacaftor/ivacaftor)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Orkambi (lumacaftor/ivacaftor)
Cystic fibrosis (CF) Indicated for the treatment of cystic fibrosis (CF) in patients age 1 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. Limitations of Use: The efficacy and safety of Orkambi have not been established in patients with CF other than those homozygous for the F508del mutation.

2 . Criteria

Product Name: Orkambi (100 mg - 125 mg) tablet

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

Product Name	Generic Name	GPI	Brand/Generic
ORKAMBI	LUMACAFTOR-IVACAFTOR TAB 100-125 MG	45309902300310	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 6 years of age or older

AND

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

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (200 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORKAMBI	LUMACAFTOR-IVACAFTOR TAB 200-125 MG	45309902300320	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 12 years of age or older

AND

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

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (100 mg - 125 mg) tablet, Orkambi (200 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORKAMBI	LUMACAFTOR-IVACAFTOR TAB 200-125 MG	45309902300320	Brand
ORKAMBI	LUMACAFTOR-IVACAFTOR TAB 100-125 MG	45309902300310	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

Product Name: Orkambi (100 mg - 125 mg) granules packet, Orkambi (150 mg - 188 mg) granules packet, Orkambi (75 mg - 94 mg) granules packet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 100-125 MG	45309902303010	Brand
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 150-188 MG	45309902303020	Brand
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 75-94 MG	45309902303005	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - One of the following:

3.1 Patient is 1 through 5 years of age

OR

3.2 Both of the following:

- Patient is 6 years of age or greater
- Patient is unable to swallow oral tablets

AND

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

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (100 mg - 125 mg) granules packet, Orkambi (150 mg - 188 mg) granules packet, Orkambi (75 mg - 94 mg) granules packet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 100-125 MG	45309902303010	Brand
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 150-188 MG	45309902303020	Brand
ORKAMBI	LUMACAFTOR-IVACAFTOR GRANULES PACKET 75-94 MG	45309902303005	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

AND

2 - One of the following:

2.1 Patient is 1 through 5 years of age

OR

2.2 Both of the following:

- Patient is 6 years of age or greater
- Patient is unable to swallow oral tablets

3 . References

1. Orkambi Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. August 2023.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160913
Guideline Name	Orserdu (elacestrant)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Orserdu (elacestrant)
Breast Cancer Indicated for the treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

2 . Criteria

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

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ORSERDU	ELACESTRANT HYDROCHLORIDE TAB 86 MG	21403720100320	Brand
ORSERDU	ELACESTRANT HYDROCHLORIDE TAB 345 MG	21403720100340	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

- Advanced
- Metastatic

AND

3 - Disease is estrogen receptor (ER)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of estrogen receptor (ESR1) mutation(s) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)] [A, 1, 3]

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

Product Name	Generic Name	GPI	Brand/Generic
ORSERDU	ELACESTRANT HYDROCHLORIDE TAB 86 MG	21403720100320	Brand
ORSERDU	ELACESTRANT HYDROCHLORIDE TAB 345 MG	21403720100340	Brand

Approval Criteria

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

3 . Endnotes

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160914
Guideline Name	Otezla (apremilast)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Otezla (apremilast)
Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis. **Plaque Psoriasis (PsO)** Indicated for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy. Indicated for pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. **Oral Ulcers Associated with Behçet's Disease** Indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

2 . Criteria

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [2]:

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

AND

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

- Dermatologist
- Rheumatologist

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis (PsA)

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

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 2]:

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

Product Name: Otezla	
Diagnosis	Plaque psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 4 X 10 MG & 51 X 20 MG	6670001500B710	Brand
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 20 MG	66700015000320	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Both of the following:

- Patient is 6 years of age or older
- Patient weighs at least 20 kg

AND

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

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Otezla	
Diagnosis	Plaque psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 4 X 10 MG & 51 X 20 MG	6670001500B710	Brand
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 20 MG	66700015000320	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

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

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

Product Name: Otezla	
Diagnosis	Oral Ulcers Associated with Behçet's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Diagnosis of Behçet's Disease

AND

2 - Patient has active oral ulcers

Product Name: Otezla	
Diagnosis	Oral Ulcers Associated with Behçet's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OTEZLA	APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG	6670001500B720	Brand
OTEZLA	APREMILAST TAB 30 MG	66700015000330	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy(e.g., reduction in pain from oral ulcers or reduction in number of oral ulcers)

3 . References

1. Otezla Prescribing Information. Amgen Inc. Thousand Oaks, CA. April 2024.
2. 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.
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. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160915
Guideline Name	PCSK9 Inhibitors - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Repatha (evolocumab)
Prevention of Cardiovascular Events Indicated in adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization. **Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia)** Indicated as an adjunct to diet, alone or in combination with other low density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C. **Heterozygous Familial Hypercholesterolemia (HeFH)** Indicated as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C **Homozygous Familial Hypercholesterolemia** Indicated as an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C

Drug Name: Praluent (alirocumab)
Prevention of Cardiovascular Events Indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease. **Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia)** Indicated as an adjunct to diet, alone or in combination with other low density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C. **Heterozygous Familial Hypercholesterolemia (HeFH)** Indicated as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 8 years and older with HeFH to reduce LDL-C. **Homozygous Familial Hypercholesterolemia** Indicated as an adjunct to other LDL-C lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

2 . Criteria

Product Name: Repatha	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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 LDL-C values while on maximally tolerated lipid-lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 One of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 70 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 One of the following:

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

OR

3.3 Both of the following:

3.3.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.3.2 LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

Product Name: Praluent (F)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular

	Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - One of the following diagnoses:

1.1 Both of the following:

- Heterozygous familial hypercholesterolemia (HeFH)
- Patient is 8 years of age or older

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD)

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following:

- Patient has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
- Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms

or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
- Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following:

3.1 One of the following LDL-C values while on maximally tolerated lipid-lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 One of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 70 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 For patients 10 years of age or older, one of the following:

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

OR

3.3 Both of the following:

3.3.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.3.2 LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

AND

4 - For patients 10 years of age or older: Trial and failure, contraindication, or intolerance to Repatha

Product Name: Repatha, Praluent (F)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REPATHA SURECLICK	EVOLOCUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML	3935002000D520	Brand
REPATHA	EVOLOCUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 140 MG/ML	3935002000E520	Brand
REPATHA PUSHTRONEX SYSTEM	EVOLOCUMAB SUBCUTANEOUS SOLN CARTRIDGE/INFUSOR 420 MG/3.5ML	3935002000E230	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline

AND

2 - One of the following:

- Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose
- Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

3 - Applies to Praluent only: For patients 10 years of age or older: Trial and failure, contraindication, or intolerance to Repatha

Product Name: Praluent (NF)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - One of the following diagnoses:

1.1 Both of the following:

- Heterozygous familial hypercholesterolemia (HeFH)
- Patient is 8 years of age or older

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD)

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following:

- Patient has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
- Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
- Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following:

3.1 Submission of medical records (e.g., laboratory values) documenting one of the following LDL-C values while on maximally tolerated lipid-lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting one of the

following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 70 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 For patients 10 years of age or older, one of the following:

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

OR

3.3 Both of the following:

3.3.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.3.2 Submission of medical records (e.g., laboratory values) documenting LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

AND

4 - For patients 10 years of age or older: Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha

Product Name: Praluent (NF)

Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline

AND

2 - One of the following:

- Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose
- Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

3 - For patients 10 years of age or older: Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha

Product Name: Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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 One of the following:

- Untreated/pre-treatment LDL-C greater than 500 mg/dL
- Treated LDL-C greater than 300 mg/dL

AND

1.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - One of the following:

- Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)
- Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Patient is 10 years of age or older

Product Name: Praluent (F)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following:

1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

OR

1.2 Both of the following:

1.2.1 One of the following:

- Untreated/pre-treatment LDL-C greater than 500 mg/dL
- Treated LDL-C greater than 300 mg/dL

AND

1.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - One of the following:

- Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)
- Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Trial and failure, contraindication, or intolerance to Repatha

Product Name: Repatha, Praluent (F)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REPATHA SURECLICK	EVOLOCUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML	3935002000D520	Brand
REPATHA	EVOLOCUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 140 MG/ML	3935002000E520	Brand
REPATHA PUSHTRONEX SYSTEM	EVOLOCUMAB SUBCUTANEOUS SOLN CARTRIDGE/INFUSOR 420 MG/3.5ML	3935002000E230	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline

AND

2 - One of the following:

- Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe)
- Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Applies to Praluent only: Trial and failure, contraindication, or intolerance to Repatha

Product Name: Praluent (NF)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 75 MG/ML	3935001000D520	Brand
PRALUENT	ALIROCUMAB SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML	3935001000D530	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following:

1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

OR

1.2 Both of the following:

1.2.1 One of the following:

- Untreated/pre-treatment LDL-C greater than 500 mg/dL
- Treated LDL-C greater than 300 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. October 2021.
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
6. Harada-Shiba M, Arai H, Ishigaki Y, Ishibashi S, Okamura T, Ogura M, Dobashi K, Nohara A, Bujo H, Miyauchi K, Yamashita S, Yokote K; Working Group by Japan Atherosclerosis Society for Making Guidance of Familial Hypercholesterolemia. Guidelines for Diagnosis and Treatment of Familial Hypercholesterolemia 2017. J Atheroscler Thromb. 2018 Aug 1;25(8):751-770. doi: 10.5551/jat.CR003. Epub 2018 Jun 7. PMID: 29877295; PMCID: PMC6099072.

5 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160916
Guideline Name	Piqray (alpelisib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Piqray (alpelisib)
Advanced or Metastatic Breast Cancer Indicated in combination with fulvestrant for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

2 . Criteria

Product Name: Piqray	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PIQRAY 200MG DAILY DOSE	ALPELISIB TAB THERAPY PACK 200 MG DAILY DOSE	2153801000B720	Brand
PIQRAY 250MG DAILY DOSE	ALPELISIB TAB PACK 250 MG DAILY DOSE (200 MG & 50 MG TABS)	2153801000B725	Brand
PIQRAY 300MG DAILY DOSE	ALPELISIB TAB PACK 300 MG DAILY DOSE (2X150 MG TAB)	2153801000B730	Brand

Approval Criteria

1 - Diagnosis of advanced or metastatic breast cancer

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Used in combination with fulvestrant

AND

6 - Disease has progressed on or after an endocrine-based regimen

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

Product Name	Generic Name	GPI	Brand/Generic
PIQRAY 200MG DAILY DOSE	ALPELISIB TAB THERAPY PACK 200 MG DAILY DOSE	2153801000B720	Brand
PIQRAY 250MG DAILY DOSE	ALPELISIB TAB PACK 250 MG DAILY DOSE (200 MG & 50 MG TABS)	2153801000B725	Brand
PIQRAY 300MG DAILY DOSE	ALPELISIB TAB PACK 300 MG DAILY DOSE (2X150 MG TAB)	2153801000B730	Brand

Approval Criteria

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

3 . References

1. Piqray Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. January 2024.

4 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160917
Guideline Name	Pomalyst (pomalidomide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Pomalyst (pomalidomide)
Multiple myeloma Indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy. **Kaposi Sarcoma** Indicated for the treatment of: 1) Adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART). 2) Kaposi sarcoma (KS) in adult patients who are HIV-negative. Note: this indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

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

Product Name	Generic Name	GPI	Brand/Generic
POMALYST	POMALIDOMIDE CAP 1 MG	21450080000110	Brand
POMALYST	POMALIDOMIDE CAP 2 MG	21450080000115	Brand
POMALYST	POMALIDOMIDE CAP 3 MG	21450080000120	Brand
POMALYST	POMALIDOMIDE CAP 4 MG	21450080000125	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

Product Name: Pomalyst	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
POMALYST	POMALIDOMIDE CAP 1 MG	21450080000110	Brand
POMALYST	POMALIDOMIDE CAP 2 MG	21450080000115	Brand
POMALYST	POMALIDOMIDE CAP 3 MG	21450080000120	Brand
POMALYST	POMALIDOMIDE CAP 4 MG	21450080000125	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of AIDS-related Kaposi sarcoma

OR

1.2 Both of the following:

1.2.1 Diagnosis of Kaposi sarcoma

AND

1.2.2 Patient is HIV-negative

Product Name: Pomalyst	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
POMALYST	POMALIDOMIDE CAP 1 MG	21450080000110	Brand
POMALYST	POMALIDOMIDE CAP 2 MG	21450080000115	Brand
POMALYST	POMALIDOMIDE CAP 3 MG	21450080000120	Brand
POMALYST	POMALIDOMIDE CAP 4 MG	21450080000125	Brand

Approval Criteria

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

3 . References

1. Pomalyst Prescribing Information, Celgene Corporation, Summit, NJ. March 2023.
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 April 22, 2024.

4 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160918
Guideline Name	Prior Authorization Administrative Guideline
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160919
Guideline Name	Prolia (denosumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Prolia (denosumab)
Treatment of postmenopausal women with osteoporosis at high risk for fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures. **Treatment to increase bone mass in men with osteoporosis at high risk for fracture** Indicated for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. **Treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer [A]** Indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures. NOTE: The

use of Prolia for the treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer should not be confused with the use of Xgeva (another injectable formulation of denosumab) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors (including breast cancer and prostate cancer).

Treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer [B] Indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. NOTE: The use of Prolia for the treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer should not be confused with the use of Xgeva (another injectable formulation of denosumab) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors (including breast cancer and prostate cancer).

Treatment of Glucocorticoid-Induced Osteoporosis Indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name: Prolia	
Diagnosis	Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
Approval Length	12 months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Diagnosis of nonmetastatic prostate cancer

AND

2 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]

2.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]

OR

2.2 Bilateral orchiectomy (i.e., surgical castration)

AND

3 - One of the following:

3.1 Age greater than or equal to 70 years [11,C]

OR

3.2 Both of the following:

3.2.1 Age less than 70 years [11]

AND

3.2.2 One of the following:

3.2.2.1 Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) [11]

OR

3.2.2.2 History of one of the following resulting from minimal trauma: [9,11]

- Vertebral compression fracture

- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., zoledronic acid) [19]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Prolia	
Diagnosis	Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
Approval Length	12 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]

1.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]

OR

1.2 Bilateral orchiectomy (i.e., surgical castration)

AND

2 - No evidence of metastases

AND

3 - Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Prolia	
Diagnosis	Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
Approval Length	12 months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12,B]

AND

3 - One of the following:

3.1 Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) [12,E]

OR

3.2 History of one of the following resulting from minimal trauma: [9]

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate) [20]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Prolia	
Diagnosis	Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
Approval Length	12 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12]

AND

2 - Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Prolia	
Diagnosis	Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Diagnosis of postmenopausal osteoporosis or osteopenia [2,5]

AND

2 - One of the following: [5,17]

2.1 Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

2.2 Both of the following:

2.2.1 BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

2.3 History of one of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

3 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Prolia	
Diagnosis	Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Prolia	
Diagnosis	Increase bone mass in men at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient is a male with osteoporosis or osteopenia

AND

2 - One of the following: [16,17]

2.1 Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

2.2 Both of the following:

2.2.1 BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score

greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

2.3 History of one of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

3 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Prolia	
Diagnosis	Increase bone mass in men at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Prolia	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	3004453000E520	Brand

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - Patient is initiating or continuing on greater than or equal to 7.5 mg/day of prednisone (or its equivalent) and is expected to remain on glucocorticoid therapy for at least 6 months

AND

3 - One of the following: [F]

3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

3.4 One of the following:

- Glucocorticoid dosing of at least 30 mg per day
- Cumulative glucocorticoid dosing of at least 5 grams per year

AND

4 - Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [G]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Prolia	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROLIA	DENOSUMAB INJ SOLN PREFILLED SYRINGE 60 MG/ML	30044530000E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Notes	If patient meets criteria above, please approve at GPI-12.

3 . Definitions

Definition	Description
Bone mineral density (BMD) [3]	A risk factor for fractures. By DXA, BMD is expressed as the amount of mineralized tissue in the area scanned (g/cm2); with QCT, BMD is expressed as the amount per volume of bone (mg/cm3). Hip BMD by DXA is considered the best predictor of hip fracture; it appears to predict other types of fractures as well as measurements made at other skeletal sites. Lumbar spine BMD may be preferable to assess changes early in menopause and after bilateral ovariectomy and may be better than hip BMD in predicting risk of spine fractures especially in women in their 50s and 60s.
Dual x-ray absorptiometry (DXA) [3]	A diagnostic test used to assess bone density at various skeletal sites using radiation exposure about one-tenth that of a standard chest X-ray. Central DXA (lumbar spine, hip) is the preferred measurement for definitive diagnosis of osteoporosis and for monitoring the effects of therapy.
Fracture [3]	Breakage of a bone, either complete or incomplete whether from trauma, repetitive stress, or bone insufficiency. Osteoporosis can contribute to any fracture at any skeletal site, but overwhelmingly affects sites that predominate in trabecular bone: femoral neck, total hip, spine, and forearm. Fractures in cortical bone dense sites are less likely to be attributed to osteoporosis, such as fingers, toes,

	skull, and face. Vertebral compression fractures are the most common type of osteoporotic fracture.
Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean BMD of a young adult reference population (T-score between − 1.0 and − 2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration of bone tissue, decreased bone strength, bone fragility, and a consequent increase in fracture risk; BMD 2.5 or more standard deviations below the mean BMD of a young adult reference population (T-score at or below − 2.5).
Peripheral DXA [3]	A DXA test used to assess bone density in the forearm, finger, and heel.
Quantitative computed tomography (QCT) [3]	A diagnostic test used to assess volumetric bone density; reflects three-dimensional BMD. Usually used to assess the lumbar spine but has been adapted for other skeletal sites (e.g., hip). It is also possible to measure trabecular and cortical bone density in the periphery by peripheral QCT (pQCT) or high-resolution pQCT (HRpQCT).
Quantitative ultrasound densitometry (QUS) [3]	A diagnostic test used to assess bone density at the calcaneus or tibia. Ultrasound measurements correlate only modestly with other assessments of bone density in the same patient, yet some prospective studies indicate that ultrasound may predict fractures as effectively as other measures of bone density.
Remodeling [3]	Also called bone turnover, remodeling is the process by which the skeleton repairs damage and maintains serum calcium levels through the ongoing lifelong dual processes of bone resorption (breakdown) and formation
Resorption [3]	The breakdown and removal of bone tissue during bone remodeling.
Risk factors [3]	For osteoporotic fractures, risk factors include low BMD, parental history of hip fracture, low body weight, previous fracture, smoking, excess alcohol intake, glucocorticoid use, secondary causes of osteoporosis (e.g., rheumatoid arthritis), and history of falls. These readily accessible and commonplace factors are associated with the risk of hip fracture and, in most cases, with that of vertebral and other types of fracture as well.
Severe or “established” osteoporosis [3]	Osteoporosis characterized by bone density that is 2.5 standard deviations or more below the young normal mean (T-score at or

	below -2.5), accompanied by the occurrence of at least one fragility-related fracture.
T-score [3]	In describing BMD, the number of standard deviations above or below the mean BMD of a young adult reference population.
Z-score [3]	In describing BMD, the number of standard deviations above or below the mean BMD for persons of the same age, sex, and ethnicity.

4 . Endnotes

A. Androgen deprivation therapy (ADT) is commonly used in the treatment of prostate cancer. ADT can be accomplished using luteinizing hormone-releasing hormone (LHRH) agonists (medical castration), also known as gonadotropin releasing hormone (GnRH) agonists, or bilateral orchiectomy (surgical castration), which are equally effective. [13] Examples of LHRH agonists include Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin).
B. Aromatase inhibitors (AIs) include selective, nonsteroidal AIs (Arimidex [anastrozole] and Femara [letrozole]) and steroidal AIs (Aromasin [exemestane]).
C. Meta-analyses have shown that advancing age increases fracture risk beyond that predicted by age related loss of BMD. Although typical changes in BMD would predict a 4-fold increase in fracture risk from ages 50 to 90 years, fracture risk actually increases 30-fold. Estimated fracture rates using FRAX calculations reflect a strong influence of older age on risk for clinical fracture. When clinical factors were used without BMD in one cross-sectional study, FRAX estimated that 76.6% of men in their 70s and virtually all men 80 years old or older exceeded the NOF recommended risk threshold for drug therapy. [14]
D. Most men run a 2-year course of androgen deprivation therapy while most women receive treatment with aromatase inhibitors for about 5 years. A one year treatment authorization is reasonable. [15]
E. Owing to the rate of bone loss associated with breast cancer treatments (i.e., aromatase inhibitors), and uncertainties about the interaction between aromatase inhibitor use and BMD for fracture risk, the threshold for intervention has been set at a higher level than that generally recommended for postmenopausal osteoporosis. [8]
F. According to the American College of Rheumatology (ACR) guidelines for the prevention and treatment of glucocorticoid-induced osteoperosis, patients considered at high risk of fractures are as follows: (a) prior osteoporotic fracture, (b) a hip or spine BMD T-score less than or equal to -2.5, or (c) FRAX 10-year risk of hip or major osteoporotic fracture at 3 percent or more and 20 percent or more, respectively. [18]
G. According to ACR, oral bisphosphonates are considered first-line for patients with glucocorticod-induced osteoperosis at high risk for fractures. For patients in whom oral bisphosphonates are not appropriate, IV bisphosphonates should be considered. [18]

5 . References

1. Prolia prescribing information. Amgen Inc. Thousand Oaks, CA. March 2024.
2. Cummings SR, Martin JS, McClung MR, et al. Denosumab for prevention of fractures in postmenopausal women with osteoporosis. NEJM. 2009;361:756-765.
3. The Bone Health and Osteoporosis Foundation (BHOF). Clinician's guide to prevention and treatment of osteoporosis. Washington (DC): The Bone Health and Osteoporosis Foundation (BHOF); 2022
4. North American Menopause Society. Management of postmenopausal osteoporosis in postmenopausal women: 2010 position statement of the North American Menopause Society. Menopause 2010;17(1):25-54.
5. 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 July 9, 2021.
6. Qaseem A, Snow V, Shekelle P, et al. Pharmacologic treatment of low bone density or osteoporosis to prevent fractures: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2008;149:404-415.
7. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract. 2010;16 Suppl 3:1-37.
8. Reid DM, Doughty J, Eastell R, et al. Guidance for the management of breast cancer treatment-induced bone loss: a consensus position statement from a UK Expert Group. Cancer Treat Rev. 2008;34 Suppl 1:S3-S18.
9. Body JJ, Bergmann P, Boonen S, et al. Management of cancer treatment-induced bone loss in early breast cancer and prostate cancer – a consensus paper of the Belgian Bone Club. Osteoporos Int. 2007;18:1439-1450.
10. Hillner BE, Ingle JN, Chlebowski RT, et al. American Society of Clinical Oncology 2003 update on the role of bisphosphonates and bone health issues in women with breast cancer. J Clin Oncol. 2003;21:4042-4057.
11. Smith MR, Egerdie B, Toriz NH, et al. Denosumab in men receiving androgen-deprivation therapy for prostate cancer. N Engl J Med. 2009;361:745-755.
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6 . Revision History

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

Prior Authorization Guideline

Guideline ID	GL-160920
Guideline Name	Promacta (eltrombopag)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Promacta (eltrombopag)
Treatment of Thrombocytopenia in Patients with Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. **Treatment of Thrombocytopenia in Patients with Hepatitis C Infection** Indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Promacta should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. Limitations of use: • Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection. **Treatment of Severe Aplastic Anemia** Indicated in combination with standard

immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia. Indicated for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

2 . Criteria

Product Name: Promacta	
Diagnosis	Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	

Approval Criteria

1 - Diagnosis of one of the following:

- Persistent ITP
- Chronic ITP
- Relapsed/refractory ITP [8]

AND

2 - Baseline platelet count is less than 30,000/mcL [2, 3, 8]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [2, 3, 8]

- Corticosteroids
- Immunoglobulins
- Splenectomy

AND

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

AND

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

Product Name: Promacta	
Diagnosis	Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand

Approval Criteria

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

Product Name: Promacta	
Diagnosis	First-Line for Severe Aplastic Anemia
Approval Length	6 Months [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand

Approval Criteria

1 - Diagnosis of severe aplastic anemia

AND

2 - Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy with any equine antithymocyte globulin plus cyclosporine, alemtuzumab, or high dose cyclophosphamide) [1]

AND

3 - Patient meets at least TWO of the following [9, 10]:

- Absolute neutrophil count < 500/mcL
- Platelet count < 20,000/mcL

- Absolute reticulocyte count < 60,000/mcL

AND

4 - Used in combination with standard immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine] and cyclosporine) [1]

AND

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

Product Name: Promacta	
Diagnosis	Refractory Severe Aplastic Anemia
Approval Length	16 weeks [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand

Approval Criteria

1 - Diagnosis of refractory severe aplastic anemia

AND

2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy with antithymocyte globulin (ATG) and cyclosporine [5-7]

AND

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

AND

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

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

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand

Approval Criteria

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

Product Name: Promacta

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

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C-associated thrombocytopenia

AND

2 - One of the following:

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

OR

2.2 Currently receiving interferon-based treatment

AND

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

- Hematologist/oncologist
- Hepatologist

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

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

Product Name	Generic Name	GPI	Brand/Generic
PROMACTA	ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)	82405030100310	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)	82405030100320	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)	82405030100330	Brand
PROMACTA	ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)	82405030100340	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)	82405030103030	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQ)	82405030103020	Brand
PROMACTA	ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQUIV)	82405030103020	Brand

Approval Criteria

1 - One of the following:

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

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

AND

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

OR

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

1.2.1 Currently on antiviral interferon therapy for treatment of chronic hepatitis C

3 . Endnotes

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

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5. Promacta product dossier. GlaxoSmithKline. Research Triangle Park, NC. 2013.

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8. Per clinical consult with hematologist/oncologist. June 20, 2018.
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10. Per clinical consult with hematologist/oncologist. January 24, 2019.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160921
Guideline Name	Provigil (modafinil), Nuvigil (armodafinil)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Provigil (modafinil)
Narcolepsy Indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy. **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. **Shift work disorder (SWD)** Indicated to improve wakefulness in adult patients with excessive sleepiness associated with shift work disorder. **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) [5,7]

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. [5,9]

Drug Name: Nuvigil (armodafinil)

Narcolepsy Indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy.

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.

Shift work disorder (SWD) Indicated to improve wakefulness in adult patients with excessive sleepiness associated with shift work disorder.

2 . Criteria

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 Months [G]
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: [1,4,10]

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) [6,10,D, F]

OR

1.2 Both of the following: [6,10,D, F]

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 [5]

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 [G]
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 armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Shift Work Disorder (SWD)
Approval Length	6 Months [G]
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: [10,12]

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 [10,12]

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 [G]
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	Fatigue due to MS (off-label) [5,7,E]
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) [5,7,E]
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) [1,4,10,A-C]

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 modafinil, Brand Provigil	
Diagnosis	Adjunctive therapy for the treatment of major depressive disorder or bipolar depression (off-label)[5,9]

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 [9]:

- 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)[5,9]
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 indicati on, except for titration purposes (Narcolepsy: 12 months, All other indi

	cations: 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) [1,4,10,A-C]

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 [3]	A sudden loss of muscle tone that leads to feelings of weakness and a loss of voluntary muscle control.
CPAP (continuous positive airway pressure) [3]	Delivers pressurized air from a machine into airways through a specially designed mask that is worn during sleep.
Multiple sleep latency test (MSLT) [3]	Assesses the severity of sleepiness by measuring the speed of falling asleep during a series of nap trials.
Narcolepsy [3]	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 [3]	One of the two basic states of sleep; consists of Stages 1, 2 (light sleep) and 3,4 (deep sleep).
Obstructive sleep apnea (OSA) [3]	The most common kind of sleep apnea. It is caused by a blockage of the upper airway.
Polysomnography [3]	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 [3]	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 American Academy of Sleep Medicine guidelines list modafinil as a standard patient care strategy (generally accepted patient-care strategy that reflects a high degree of clinical certainty). [2]
B. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy with cataplexy (narcolepsy type 1) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. One or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT); or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than 110 pg/mL or one-third of the normative values with the same standardized assay). 3. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [10,11]
C. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy without cataplexy (narcolepsy type 2) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. Cataplexy is absent 3. CSF hypocretin-1 levels, if measured, must not meet the narcolepsy type 1 criterion. 4. A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT). 5. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [10.11]
D. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for obstructive sleep apnea-hypopnea syndrome (OSAHS) include: One of the following: 1. 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. [10, F, G]

E. Despite lack of good clinical evidence or statement/guideline from a professional society, use of modafinil for fatigue is considered the standard practice in MS patients [8].
F. Examples of obstructive respiratory events include: obstructive and mixed apneas, hypopneas, or respiratory effort related arousals (RERA) [10].
G. 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. [1,4]

5 . References

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6 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160922
Guideline Name	Pulmonary Arterial Hypertension Agents
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Adcirca (tadalafil) Tablets, Alyq (tadalafil) Tablets, Tadliq (tadalafil) Oral Suspension
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with New York Heart Association (NYHA) Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).
Drug Name: Adempas (riociguat) Tablets
Pulmonary Arterial Hypertension (PAH) Indicated for treatment of adults with PAH (WHO Group I) to improve exercise capacity, WHO Functional Class, and to delay clinical worsening. Efficacy was shown in patients on riociguat monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominantly patients with WHO Functional Class II to III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%).

Chronic-Thromboembolic Pulmonary Hypertension (CTEPH) Indicated for treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO Functional Class.

Drug Name: Flolan (epoprostenol sodium) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly (97%) patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (49%) or PAH associated with connective tissue diseases (51%).

Drug Name: Letairis (ambrisentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to 1) improve exercise ability and delay clinical worsening and 2) in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (60%) or PAH associated with connective tissue diseases (34%).

Drug Name: Liqrev (sildenafil) suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

Drug Name: Opsumit (macitentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to reduce the risks of disease progression and hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

Drug Name: Orenitram (treprostinil) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to delay disease progression and to improve exercise capacity. The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).

Drug Name: Opsynvi (macitentan/ tadalafil) Tablets

Pulmonary Arterial Hypertension Indicated for the chronic treatment of adults with pulmonary arterial hypertension (PAH, WHO Group I and WHO Functional Class (FC) II–III).

Macitentan reduces the risk of clinical worsening events and hospitalization. Tadalafil improves exercise ability.

Drug Name: Remodulin (treprostinil sodium) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%). Indicated to diminish the rate of clinical deterioration in patients with PAH requiring transition from epoprostenol. Consider the risks and benefits of each drug prior to transition.

Drug Name: Revatio (sildenafil) Injection, Tablets, Oral Suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I): 1) In adults to improve exercise ability and delay clinical worsening. 2) in pediatric patients 1 to 17 years old to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underlie improvements in exercise.

Drug Name: Tracleer (bosentan) Tablets, Tablets for Suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I): 1) In adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to right shunts (18%). 2) In pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.

Drug Name: Tyvaso (treprostinil) Inhalation Solution, Tyvaso (treprostinil) DPI Inhalation Powder

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities. While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

Pulmonary Hypertension Associated with Interstitial Lung Disease (ILD) Indicated for the treatment of pulmonary hypertension associated with ILD (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary

fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).
Drug Name: Veletri (epoprostenol) Injection
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.
Drug Name: Ventavis (iloprost) Inhalation Solution
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration. Studies establishing effectiveness included predominately patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (65%) or PAH associated with connective tissue diseases (23%).
Drug Name: Uptravi (selexipag) Tablets and Injection
Pulmonary Arterial Hypertension Indicated for the treatment of PAH (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with WHO Functional Class II-III symptoms. Patients had idiopathic and heritable PAH (58%), PAH associated with connective tissue disease (29%), PAH associated with congenital heart disease with repaired shunts (10%).
Drug Name: Winrevair (sotatercept-csrk) Injection
Pulmonary Arterial Hypertension Indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group I) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.

2 . Criteria

Product Name: Generic Alyq tablet, Generic tadalafil tablet, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Generic ambrisentan tablet, Opsumit tablet, Orenitram tablet, Generic treprostinil injection, Generic sildenafil tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FLOLAN	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Brand
EPOPROSTENOL SODIUM	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Generic
FLOLAN	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Brand
EPOPROSTENOL SODIUM	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Generic
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
VENTAVIS	ILOPROST INHALATION SOLUTION 10 MCG/ML	40170060002020	Brand
VENTAVIS	ILOPROST INHALATION SOLUTION 20 MCG/ML	40170060002040	Brand
VELETRI	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Brand
VELETRI	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Brand
SILDENAFIL CITRATE	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Generic
TYVASO STARTER	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO REFILL	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
OPSUMIT	MACITENTAN TAB 10 MG	40160050000320	Brand
ADEMPAS	RIOCIGUAT TAB 0.5 MG	40134050000310	Brand
ADEMPAS	RIOCIGUAT TAB 1 MG	40134050000320	Brand
ADEMPAS	RIOCIGUAT TAB 1.5 MG	40134050000330	Brand
ADEMPAS	RIOCIGUAT TAB 2 MG	40134050000340	Brand
ADEMPAS	RIOCIGUAT TAB 2.5 MG	40134050000350	Brand
SILDENAFIL	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Generic
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 0.125 MG (BASE EQUIV)	40170080050410	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 0.25 MG (BASE EQUIV)	40170080050415	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 1 MG (BASE EQUIV)	40170080050420	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 2.5 MG (BASE EQUIV)	40170080050425	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 5 MG (BASE EQUIV)	40170080050435	Brand
TRACLEER	BOSENTAN TAB FOR ORAL SUSP 32 MG	40160015007320	Brand

TADALAFIL	TADALAFIL TAB 20 MG (PAH)	40143080000320	Generic
ALYQ	TADALAFIL TAB 20 MG (PAH)	40143080000320	Generic
AMBRISENTAN	AMBRISENTAN TAB 5 MG	40160007000310	Generic
AMBRISENTAN	AMBRISENTAN TAB 10 MG	40160007000320	Generic
TYVASO REFILL	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO STARTER	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
BOSENTAN	BOSENTAN TAB 62.5 MG	40160015000320	Generic
BOSENTAN	BOSENTAN TAB 125 MG	40160015000330	Generic
TREPROSTINIL	TREPROSTINIL INJ SOLN 20 MG/20ML (1 MG/ML)	40170080002050	Generic
TREPROSTINIL	TREPROSTINIL INJ SOLN 50 MG/20ML (2.5 MG/ML)	40170080002060	Generic
TREPROSTINIL	TREPROSTINIL INJ SOLN 100 MG/20ML (5 MG/ML)	40170080002070	Generic
TREPROSTINIL	TREPROSTINIL INJ SOLN 200 MG/20ML (10 MG/ML)	40170080002080	Generic
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 16 MCG/CARTRIDGE	40170080002920	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 32 MCG/CARTRIDGE	40170080002930	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 48 MCG/CARTRIDGE	40170080002940	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 64 MCG/CARTRIDGE	40170080002950	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 112 X 32MCG & 112 X 48MCG	40170080002960	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWDER 112 X 16MCG & 84 X 32MCG	40170080002970	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWD 112 X 16MCG & 112 X 32MCG & 28 X 48MCG	40170080002980	Brand
ORENITRAM TITRATION KIT MONTH 1	TREPROSTINIL TAB ER TITR PK (MO1) 126 X0.125MG & 42 X0.25MG	4017008005C110	Brand
ORENITRAM TITRATION KIT MONTH 2	TREPROSTINIL TAB ER TITR PK (MO2) 126 X0.125MG & 210 X0.25MG	4017008005C120	Brand

ORENITRAM TITRATION KIT MONTH 3	TREPROSTINIL TAB ER TITR PK(MO3)126X0.125MG&42X0.25MG&84X1MG	4017008005C130	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Brand Adcirca tablet, Tadliq oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADCIRCA	TADALAFIL TAB 20 MG (PAH)	40143080000320	Brand
TADLIQ	TADALAFIL ORAL SUSP 20 MG/5ML (PAH)	40143080001820	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic tadalfil

Product Name: Brand Letairis tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LETAIRIS	AMBRISENTAN TAB 5 MG	40160007000310	Brand
LETAIRIS	AMBRISENTAN TAB 10 MG	40160007000320	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic ambrisentan

Product Name: Opsynvi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
OPSYNVI	MACITENTAN-TADALAFIL TAB 10-20 MG	40995502500310	Brand
OPSYNVI	MACITENTAN-TADALAFIL TAB 10-40 MG	40995502500320	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

1.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

2 - One of the following:

2.1 Trial and failure, contraindication or intolerance to generic ambrisentan

OR

2.2 Patient is currently being treated with a macitentan-containing product

AND

2 - Patient is unable to take Opsumit and generic tadalafil separately due to intolerance with Opsumit (e.g., allergy to excipient)

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Brand Remodulin injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REMODULIN	TREPROSTINIL INJ SOLN 20 MG/20ML (1 MG/ML)	40170080002050	Brand
REMODULIN	TREPROSTINIL INJ SOLN 50 MG/20ML (2.5 MG/ML)	40170080002060	Brand
REMODULIN	TREPROSTINIL INJ SOLN 100 MG/20ML (5 MG/ML)	40170080002070	Brand
REMODULIN	TREPROSTINIL INJ SOLN 200 MG/20ML (10 MG/ML)	40170080002080	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic treprostinil

Product Name: Brand Revatio tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVATIO	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic sildenafil tablet

Product Name: Brand Tracleer tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TRACLEER	BOSENTAN TAB 62.5 MG	40160015000320	Brand
TRACLEER	BOSENTAN TAB 125 MG	40160015000330	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist

- Cardiologist

AND

5 - Trial and failure or intolerance to generic bosentan tablet

Product Name: Brand Revatio injection or Generic sildenafil injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVATIO	SILDENAFIL CITRATE IV SOLN 10 MG/12.5ML (BASE EQUIVALENT)	40143060102020	Brand
SILDENAFIL	SILDENAFIL CITRATE IV SOLN 10 MG/12.5ML (BASE EQUIVALENT)	40143060102020	Generic

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Patient is unable to take oral medications [2]

AND

6 - For Brand Revatio injection, trial and failure or intolerance to generic sildenafil injection

Product Name: Liqrev, Brand Revatio oral suspension or Generic sildenafil oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVATIO	SILDENAFIL CITRATE FOR SUSPENSION 10 MG/ML	40143060101920	Brand
SILDENAFIL CITRATE	SILDENAFIL CITRATE FOR SUSPENSION 10 MG/ML	40143060101920	Generic
LIQREV	SILDENAFIL CITRATE ORAL SUSP 10 MG/ML	40143060101825	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - For Brand Revatio oral suspension, trial and failure, or intolerance to both of the following:

- Generic sildenafil tablets
- Generic sildenafil oral suspension

AND

6 - For Liqrev, trial and failure or intolerance to generic sildenafil suspension

Product Name: Adempas tablet

Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADEMPAS	RIOCIGUAT TAB 0.5 MG	40134050000310	Brand
ADEMPAS	RIOCIGUAT TAB 1 MG	40134050000320	Brand
ADEMPAS	RIOCIGUAT TAB 1.5 MG	40134050000330	Brand
ADEMPAS	RIOCIGUAT TAB 2 MG	40134050000340	Brand
ADEMPAS	RIOCIGUAT TAB 2.5 MG	40134050000350	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

AND

1.1.2 CTEPH is symptomatic

OR

1.2 Patient is currently on any therapy for the diagnosis of CTEPH

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist

- Cardiologist

Product Name: Tyvaso inhalation solution, Tyvaso Refill inhalation solution, or Tyvaso Start inhalation solution, Tyvaso DPI	
Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO STARTER	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO REFILL	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO REFILL	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO STARTER	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 16 MCG/CARTRIDGE	40170080002920	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 32 MCG/CARTRIDGE	40170080002930	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 48 MCG/CARTRIDGE	40170080002940	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 64 MCG/CARTRIDGE	40170080002950	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 112 X 32MCG & 112 X 48MCG	40170080002960	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWDER 112 X 16MCG & 84 X 32MCG	40170080002970	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWD 112 X 16MCG & 112 X 32MCG & 28 X 48MCG	40170080002980	Brand

Approval Criteria

1 - Diagnosis of pulmonary hypertension associated with interstitial lung disease

AND

2 - Diagnosis of pulmonary hypertension associated with interstitial lung disease was confirmed by diagnostic test(s) (e.g., right heart catheterization, doppler echocardiogram, computerized tomography imaging)

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Brand Adcirca tablet, Generic tadalafil tablet, Generic Alyq tablet, Tadliq oral suspension, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Brand Letairis tablet, Liqrev, Generic ambrisentan tablet, Opsynvi tablet, Opsumit tablet, Orenitram tablet, Brand Remodulin injection, Generic treprostinil injection, Brand Revatio injection, Generic sildenafil injection, Brand Revatio tablet, Generic sildenafil tablet, Brand Revatio oral suspension, Generic sildenafil oral suspension, Brand Tracleer tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution

Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ADCIRCA	TADALAFIL TAB 20 MG (PAH)	40143080000320	Brand
LETAIRIS	AMBRISENTAN TAB 5 MG	40160007000310	Brand
LETAIRIS	AMBRISENTAN TAB 10 MG	40160007000320	Brand

TRACLEER	BOSENTAN TAB 62.5 MG	40160015000320	Brand
TRACLEER	BOSENTAN TAB 125 MG	40160015000330	Brand
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
VENTAVIS	ILOPROST INHALATION SOLUTION 10 MCG/ML	40170060002020	Brand
VENTAVIS	ILOPROST INHALATION SOLUTION 20 MCG/ML	40170060002040	Brand
FLOLAN	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Brand
EPOPROSTENOL SODIUM	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Generic
FLOLAN	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Brand
EPOPROSTENOL SODIUM	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Generic
VELETRI	EPOPROSTENOL SODIUM FOR INJ 0.5 MG	40170040102110	Brand
VELETRI	EPOPROSTENOL SODIUM FOR INJ 1.5 MG	40170040102130	Brand
OPSUMIT	MACITENTAN TAB 10 MG	40160050000320	Brand
ADEMPAS	RIOCIGUAT TAB 0.5 MG	40134050000310	Brand
ADEMPAS	RIOCIGUAT TAB 1 MG	40134050000320	Brand
ADEMPAS	RIOCIGUAT TAB 1.5 MG	40134050000330	Brand
ADEMPAS	RIOCIGUAT TAB 2 MG	40134050000340	Brand
ADEMPAS	RIOCIGUAT TAB 2.5 MG	40134050000350	Brand
REVATIO	SILDENAFIL CITRATE IV SOLN 10 MG/12.5ML (BASE EQUIVALENT)	40143060102020	Brand
REVATIO	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Brand
SILDENAFIL CITRATE	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Generic
TYVASO STARTER	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO REFILL	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
SILDENAFIL	SILDENAFIL CITRATE TAB 20 MG	40143060100320	Generic
SILDENAFIL	SILDENAFIL CITRATE IV SOLN 10 MG/12.5ML (BASE EQUIVALENT)	40143060102020	Generic
TRACLEER	BOSENTAN TAB FOR ORAL SUSP 32 MG	40160015007320	Brand
TADALAFIL	TADALAFIL TAB 20 MG (PAH)	40143080000320	Generic
ALYQ	TADALAFIL TAB 20 MG (PAH)	40143080000320	Generic
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 0.125 MG (BASE EQUIV)	40170080050410	Brand

ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 0.25 MG (BASE EQUIV)	40170080050415	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 1 MG (BASE EQUIV)	40170080050420	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 2.5 MG (BASE EQUIV)	40170080050425	Brand
ORENITRAM	TREPROSTINIL DIOLAMINE TAB ER 5 MG (BASE EQUIV)	40170080050435	Brand
AMBRISENTAN	AMBRISENTAN TAB 10 MG	40160007000320	Generic
AMBRISENTAN	AMBRISENTAN TAB 5 MG	40160007000310	Generic
BOSENTAN	BOSENTAN TAB 62.5 MG	40160015000320	Generic
BOSENTAN	BOSENTAN TAB 125 MG	40160015000330	Generic
SILDENAFIL CITRATE	SILDENAFIL CITRATE FOR SUSPENSION 10 MG/ML	40143060101920	Generic
REMODULIN	TREPROSTINIL INJ SOLN 20 MG/20ML (1 MG/ML)	40170080002050	Brand
TREPROSTINIL	TREPROSTINIL INJ SOLN 20 MG/20ML (1 MG/ML)	40170080002050	Generic
REMODULIN	TREPROSTINIL INJ SOLN 50 MG/20ML (2.5 MG/ML)	40170080002060	Brand
TREPROSTINIL	TREPROSTINIL INJ SOLN 50 MG/20ML (2.5 MG/ML)	40170080002060	Generic
REMODULIN	TREPROSTINIL INJ SOLN 100 MG/20ML (5 MG/ML)	40170080002070	Brand
TREPROSTINIL	TREPROSTINIL INJ SOLN 100 MG/20ML (5 MG/ML)	40170080002070	Generic
REMODULIN	TREPROSTINIL INJ SOLN 200 MG/20ML (10 MG/ML)	40170080002080	Brand
TREPROSTINIL	TREPROSTINIL INJ SOLN 200 MG/20ML (10 MG/ML)	40170080002080	Generic
TYVASO	TREPROSTINIL INHALATION SOLUTION 0.6 MG/ML	40170080002020	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 16 MCG/CARTRIDGE	4017008000292	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 32 MCG/CARTRIDGE	40170080002930	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 48 MCG/CARTRIDGE	40170080002940	Brand
TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 64 MCG/CARTRIDGE	40170080002950	Brand

TYVASO DPI MAINTENANCE KIT	TREPROSTINIL INH POWDER 112 X 32MCG & 112 X 48MCG	40170080002960	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWDER 112 X 16MCG & 84 X 32MCG	40170080002970	Brand
TYVASO DPI TITRATION KIT	TREPROSTINIL INH POWD 112 X 16MCG & 112 X 32MCG & 28 X 48MCG	40170080002980	Brand
TADLIQ	TADALAFIL ORAL SUSP 20 MG/5ML (PAH)	40143080001820	Brand
ORENITRAM TITRATION KIT MONTH 1	TREPROSTINIL TAB ER TITR PK (MO1) 126 X0.125MG & 42 X0.25MG	4017008005C110	Brand
ORENITRAM TITRATION KIT MONTH 2	TREPROSTINIL TAB ER TITR PK (MO2) 126 X0.125MG & 210 X0.25MG	4017008005C120	Brand
ORENITRAM TITRATION KIT MONTH 3	TREPROSTINIL TAB ER TITR PK(MO3)126X0.125MG&42X0.25MG&84X1MG	4017008005C130	Brand
LIQREV	SILDENAFIL CITRATE ORAL SUSP 10 MG/ML	40143060101825	Brand
REVATIO	SILDENAFIL CITRATE FOR SUSPENSION 10 MG/ML	40143060101920	Brand
OPSYNVI	MACITENTAN-TADALAFIL TAB 10-20 MG	40995502500310	Brand
OPSYNVI	MACITENTAN-TADALAFIL TAB 10-40 MG	40995502500320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - For Brand Revatio injection, Brand Tracleer, Brand Adcirca, Brand Letairis, Brand Remodulin injection, and Brand Revatio tablet, trial and failure or intolerance to its generic counterpart

AND

3 - For Brand Revatio oral suspension, trail and failure or intolerance to both of the following:

- Generic sildenafil tablets
- Generic sildenafil oral suspension

AND

4 - For Tadliq oral suspension, trial and failure or intolerance to generic tadalafil

AND

5 - For Liqrev, trial and failure or intolerance to generic sildenafil suspension

AND

6 - For Opsynvi, patient is unable to take Opsumit and generic tadalafil separately due to intolerance with Opsumit (e.g., allergy to excipient)

Product Name: Uptravi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UPTRAVI	SELEXIPAG TAB THERAPY PACK 200 MCG (140) & 800 MCG (60)	4012007000B720	Brand
UPTRAVI	SELEXIPAG TAB 200 MCG	40120070000310	Brand
UPTRAVI	SELEXIPAG TAB 400 MCG	40120070000315	Brand
UPTRAVI	SELEXIPAG TAB 600 MCG	40120070000320	Brand
UPTRAVI	SELEXIPAG TAB 800 MCG	40120070000325	Brand
UPTRAVI	SELEXIPAG TAB 1000 MCG	40120070000330	Brand
UPTRAVI	SELEXIPAG TAB 1200 MCG	40120070000335	Brand
UPTRAVI	SELEXIPAG TAB 1400 MCG	40120070000340	Brand
UPTRAVI	SELEXIPAG TAB 1600 MCG	40120070000345	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to one of the following:

- PDE-5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)]
- Adempas (riociguat)

AND

4.1.2 Trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Uptravi injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UPTRAVI	SELEXIPAG FOR IV SOLN 1800 MCG	40120070002120	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to one of the following:

- PDE-5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)]
- Adempas (riociguat)

AND

4.1.2 Trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

6 - Patient is unable to take oral medications [13]

Product Name: Uptravi tablet/injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
UPTRAVI	SELEXIPAG TAB THERAPY PACK 200 MCG (140) & 800 MCG (60)	4012007000B720	Brand
UPTRAVI	SELEXIPAG TAB 200 MCG	40120070000310	Brand
UPTRAVI	SELEXIPAG TAB 400 MCG	40120070000315	Brand
UPTRAVI	SELEXIPAG TAB 600 MCG	40120070000320	Brand
UPTRAVI	SELEXIPAG TAB 800 MCG	40120070000325	Brand
UPTRAVI	SELEXIPAG TAB 1000 MCG	40120070000330	Brand
UPTRAVI	SELEXIPAG TAB 1200 MCG	40120070000335	Brand
UPTRAVI	SELEXIPAG TAB 1400 MCG	40120070000340	Brand
UPTRAVI	SELEXIPAG TAB 1600 MCG	40120070000345	Brand
UPTRAVI	SELEXIPAG FOR IV SOLN 1800 MCG	40120070002120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Winrevair Injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 45 MG	40110070206420	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 60 MG	40110070206425	Brand

WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 2 X 45 MG	40110070206430	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 2 X 60 MG	40110070206435	Brand

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - Patient is currently on at least two therapies indicated for the treatment of pulmonary arterial hypertension from the following different mechanisms of action, unless there is a contraindication or intolerance:

- Endothelin receptor antagonists (i.e., Bosentan, ambrisentan or macitentan)
- Phosphodiesterase 5 inhibitors (i.e., Tadalafil or sildenafil)

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Winrevair Injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 45 MG	40110070206420	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 60 MG	40110070206425	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 2 X 45 MG	40110070206430	Brand
WINREVAIR	SOTATERCEPT-CSRK FOR SUBCUTANEOUS SOLN KIT 2 X 60 MG	40110070206435	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160923
Guideline Name	Pulmozyme (dornase alfa inhalation solution)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Pulmozyme (dornase alpha) Inhalation Solution
Cystic Fibrosis Indicated, in conjunction with standard therapies, for the management of pediatric and adult patients with cystic fibrosis (CF) to improve pulmonary function. In CF patients with an FVC ≥ 40% of predicted, daily administration of PULMOZYME has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

2 . Criteria

Product Name: Pulmozyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PULMOZYME	DORNASE ALFA INHAL SOLN 1 MG/ML	45304020002010	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF) [2,3]

Product Name: Pulmozyme	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
PULMOZYME	DORNASE ALFA INHAL SOLN 1 MG/ML	45304020002010	Brand
PULMOZYME	DORNASE ALFA INHAL SOLN 2.5 MG/2.5ML	45304020002010	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient demonstrates positive clinical response (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations) to therapy

3 . References

1. Pulmozyme Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2024.

2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013;187(7):680-9.
3. Flume PA, O'Sullivan BP, Robinson KA et al. Cystic fibrosis pulmonary guidelines. Am J Respir Crit Care Med. 2007;176:957-969

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160924
Guideline Name	Qinlock (ripretinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Qinlock (ripretinib)
Gastrointestinal Stromal Tumor (GIST) Indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

2 . Criteria

Product Name: Qinlock	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QINLOCK	RIPRETINIB TAB 50 MG	21533053000320	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Disease is advanced

AND

3 - Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib

Product Name: Qinlock	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
QINLOCK	RIPRETINIB TAB 50 MG	21533053000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Qinlock Prescribing Information. Deciphera Pharmaceuticals, LLC. Waltham, MA. October 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160925
Guideline Name	Quantity Limit General
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name: Drugs subjected to Quantity Limits (in the absence of a drug-specific guideline)*	
Approval Length	6 Month(s) (except for titration or loading-dose purposes)
Guideline Type	Administrative

Product Name	Generic Name	GPI	Brand/Generic
Quantity limit general			
Quantity			

Approval Criteria

1 - One of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - One of the following:

2.1 For titration or loading-dose purposes (one time authorization or per FDA labeling)

OR

2.2 Requested strength/dose is commercially unavailable**

OR

2.3 Patient is on a dose alternating schedule

OR

2.4 For topical applications, member has tried the dose under the quantity limit restriction for an adequate period of time and it has been deemed ineffective or insufficient in the treatment of the member's disease or medical condition

AND

3 - For the indication being requested, the higher dose, frequency of administration, and quantity are supported in one of the following:

3.1 The dosage and administration section of the manufacturer's prescribing information

OR

3.2 One of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

OR

3.3 Supported as being generally safe and effective by clinical research in two articles from peer reviewed medical journals

Notes	*This guideline only applies in the absence of a drug-specific quantity l imit override guideline. No override requests will be permitted for acet aminophen, alone or in combination with other agents, which will exce ed a total of 4 grams of acetaminophen per day. **Commercially avail able strength/dose requires a formulary drug.

2 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160926
Guideline Name	Reblozyl (luspatercept-aamt)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Reblozyl (luspatercept-aamt)
Beta Thalassemia Indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia. **Myelodysplastic Syndromes with Ring Sideroblasts or Myelodysplastic/ Myeloproliferative Neoplasm with Ring Sideroblasts and Thrombocytosis Associated Anemia** Indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia. **Myelodysplastic Syndromes Associated Anemia** Indicated for the treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very

low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions. Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

2 . Criteria

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 25 MG	82400540102120	Brand
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 75 MG	82400540102140	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of beta thalassemia major [3]

AND

1.1.2 Patient requires regular red blood cell (RBC) transfusions

OR

1.2 Diagnosis of transfusion-dependent beta thalassemia [3]

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 25 MG	82400540102120	Brand
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 75 MG	82400540102140	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in RBC transfusion burden) [1,2]

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 25 MG	82400540102120	Brand
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 75 MG	82400540102140	Brand

Approval Criteria

1 - One of the following diagnoses:

1.1 Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS)

OR

1.2 Myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

AND

2 - Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 25 MG	82400540102120	Brand
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 75 MG	82400540102140	Brand

Approval Criteria

1 - Diagnosis of very low- to intermediate-risk myelodysplastic syndromes (MDS)

AND

2 - Patient does not have previous erythropoiesis stimulating agent use (ESA-naïve)

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 25 MG	82400540102120	Brand
REBLOZYL	LUSPATERCEPT-AAMT FOR SUBCUTANEOUS INJ 75 MG	82400540102140	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., RBC transfusion independence, improvement in hemoglobin levels) [1,4]

3 . References

1. Reblozyl Prescribing Information. Celgene Corporation. Summit, NJ. August 2023.
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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160927
Guideline Name	Regranex (becaplermin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Regranex Gel (becaplermin)
Diabetic Neuropathic Ulcers Indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, when used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control. Limitations of Use: The efficacy of Regranex Gel has not been established for the treatment of pressure ulcers and venous stasis ulcers and has not been evaluated for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue (Stage I or II, IAET staging classification) or ischemic diabetic ulcers. The effects of becaplermin on exposed joints, tendons, ligaments, and bone have not been established in humans. Regranex is not intended to be used in wounds that close by primary intention.

2 . Criteria

Product Name: Regranex	
Approval Length	5 Months [1, A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REGRANEX	BECAPLERMIN GEL 0.01%	90945020004020	Brand

Approval Criteria

1 - Patient has a lower extremity diabetic neuropathic ulcer

AND

2 - Treatment will be given in combination with ulcer wound care (e.g., debridement, infection control, and/or pressure relief) [1]

3 . Endnotes

A. Fifty percent of patients will achieve complete healing within 20 weeks with Regranex. Reassessment is required for further therapy. [1] If the ulcer does not decrease in size by approximately 30% after 10 weeks of treatment or complete healing has not occurred in 20 weeks, continued treatment with Regranex should be reassessed. Postmarketing studies have demonstrated an increased risk of mortality secondary to malignancy observed in patients treated with greater than or equal to 3 tubes of Regranex gel. [1]

4 . References

1. Regranex Prescribing Information. Smith & Nephew, Inc. Fort Worth, TX. August 2019.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160928
Guideline Name	Repository Corticotropin Gel Products - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Acthar Gel (repository corticotropin injection)
Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. **Exacerbations of Multiple Sclerosis [4, 5]** Indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease. **All Other Disease States [A]** *Please Note: The request for Acthar for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions. **[Non-Approvable Use] Rheumatic Disorders* [6, 7, A]** As adjunctive therapy for short-term

administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis.

[Non-Approvable Use] Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

[Non-Approvable Use] Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome.

[Non-Approvable Use] Allergic States* [A] Serum sickness.

[Non-Approvable Use] Ophthalmic Diseases* [14, A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation.

[Non-Approvable Use] Respiratory Diseases* [11, A] Symptomatic sarcoidosis

[Non-Approvable Use] Edematous State* [12, 13, 15, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Drug Name: Purified Cortrophin Gel (repository corticotropin injection)

Exacerbations of Multiple Sclerosis [4, 5] Indicated for acute exacerbations of multiple sclerosis.

All Other Disease States [A] *Please Note: The request for Purified Cortrophin Gel for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions.

[Non-Approvable Use] Rheumatic Disorders* [6, 7, A] Indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis; Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); Ankylosing spondylitis; Acute gouty arthritis.

[Non-Approvable Use] Collagen Diseases* [8-10, A] Indicated during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

[Non-Approvable Use] Dermatologic Diseases* [A] Indicated for severe erythema multiforme (Stevens-Johnson syndrome), severe psoriasis.

[Non-Approvable Use] Allergic States* [A] Indicated for atopic dermatitis, serum sickness.

[Non-Approvable Use] Ophthalmic Diseases* [14, A] Indicated for severe acute and

chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation.

[Non-Approvable Use] Respiratory Diseases* [11, A] Indicated for symptomatic sarcoidosis.

[Non-Approvable Use] Edematous States* [12, 13, 15, A] Indicated to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Off Label Uses: Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

2 . Criteria

Product Name: Acthar Gel 80 unit/mL vial, Purified Cortrophin Gel [off-label]	
Diagnosis	Infantile Spasms (West Syndrome)
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
CORTROPHIN	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand

Approval Criteria

1 - Diagnosis of infantile spasms (West Syndrome)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Patient is less than 2 years of age

Product Name: Acthar Gel, Purified Cortrophin Gel	
Diagnosis	Multiple Sclerosis
Approval Length	3 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
CORTROPHIN	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 40 UNIT/0.5ML	3030001000D420	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 80 UNIT/ML	3030001000D430	Brand

Approval Criteria

1 - Diagnosis of acute exacerbation of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - One of the following:

3.1 Both of the following:

- Patient is new to therapy with corticotropin
- Trial and failure, contraindication, or intolerance to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone)

OR

3.2 All of the following:

- Patient's multiple sclerosis exacerbations have been treated in the past with corticotropin
- Patient has benefitted from treatment with corticotropin for acute exacerbations of multiple sclerosis
- Medication is being used to treat a new exacerbation of multiple sclerosis

Product Name: Acthar Gel, Purified Cortrophin Gel	
Diagnosis	All Other Indications [A]
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
CORTROPHIN	CORTICOTROPIN INJ GEL 80 UNIT/ML	30300010004010	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 40 UNIT/0.5ML	3030001000D420	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 80 UNIT/ML	3030001000D430	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 40 unit/0.5 mL auto-injector, Acthar gel 80 unit/mL auto-injector

Diagnosis	Multiple Sclerosis
Approval Length	3 Week(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 40 UNIT/0.5ML	3030001000D420	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 80 UNIT/ML	3030001000D430	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of acute exacerbation of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Both of the following:

- Patient is new to therapy with corticotropin
- Trial and failure, contraindication, or intolerance to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone)

OR

3.2 All of the following:

- Patient's multiple sclerosis exacerbations have been treated in the past with corticotropin
- Patient has benefitted from treatment with corticotropin for acute exacerbations of multiple sclerosis

- Medication is being used to treat a new exacerbation of multiple sclerosis

Product Name: Acthar Gel 40 unit/0.5 mL auto-injector, Acthar gel 80 unit/mL auto-injector	
Diagnosis	All Other Indications [A]
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 40 UNIT/0.5ML	3030001000D420	Brand
ACTHAR GEL	CORTICOTROPIN SUBCUTANEOUS GEL AUTO-INJECTOR 80 UNIT/ML	3030001000D430	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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160929
Guideline Name	Restasis (cyclosporine 0.05%) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 (Tier 1*)	
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

Notes	NOTE: *This criteria is to be used for generic cyclosporine 0.05% ophthalmic emulsion that is on Tier 1 ONLY. This criteria does NOT apply to generic cyclosporine 0.05% ophthalmic emulsion on Tier 2 or Tier 3.

Product Name: Generic cyclosporine 0.05% ophthalmic emulsion (Tier 2 or Tier 3*)	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
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

AND

3 - All of the following:

3.1 At least 6 months use of brand Restasis within the previous 365 days (document drug, duration, and date of use)

AND

3.2 Documentation provided stating that brand Restasis has not been effective

AND

3.3 Justification provided for why the generic is expected to provide benefit when brand Restasis has not been shown to be effective

Notes	Note: *This criteria is to be used for generic cyclosporine 0.05% ophth almic emulsion that is on Tier 2 or Tier 3 ONLY. This criteria does NO T apply to generic cyclosporine 0.05% ophthalmic emulsion on Tier 1.

Product Name: Brand Restasis, generic cyclosporine 0.05% ophthalmic emulsion (Tier 1*)	
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 - Patient demonstrates 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])

Notes	NOTE: *This criteria is to be used for generic cyclosporine 0.05% opht halmic emulsion that is on Tier 1 ONLY. This criteria does NOT apply

	to generic cyclosporine 0.05% ophthalmic emulsion on Tier 2 or Tier 3 .

Product Name: Generic cyclosporine 0.05% ophthalmic emulsion (Tier 2 or Tier 3*)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CYCLOSPORINE	CYCLOSPORINE (OPHTH) EMULSION 0.05%	86720020001620	Generic

Approval Criteria

1 - Patient demonstrates 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])

AND

3 - All of the following:

3.1 At least 6 months use of brand Restasis within the previous 365 days (document drug, duration, and date of use)

AND

3.2 Documentation provided stating that brand Restasis has not been effective

AND

3.3 Justification provided for why the generic is expected to provide benefit when brand Restasis has not been shown to be effective

Notes	Note: *This criteria is to be used for generic cyclosporine 0.05% ophthalmic emulsion that is on Tier 2 or Tier 3 ONLY. This criteria does NOT apply to generic cyclosporine 0.05% ophthalmic emulsion on Tier 1.

Product Name: Generic cyclosporine 0.05% ophthalmic emulsion	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
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

AND

3 - All of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming at least 6 months use of brand Restasis within the previous 365 days (document drug, duration, and date of use)

AND

3.2 Submission of documentation provided stating that brand Restasis has not been effective

AND

3.3 Submission of justification provided for why the generic is expected to provide benefit when brand Restasis has not been shown to be effective

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160930
Guideline Name	Retevmo (selpercatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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. 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). **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. May 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160931
Guideline Name	Revcovi (elapegademase-lvlr)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Revcovi (elapegademase-lvlr)
Adenosine deaminase severe combined immune deficiency (ADA-SCID) Indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.

2 . Criteria

Product Name: Revcovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVCOVI	ELAPEGADEMASE-LVLR IM SOLN 2.4 MG/1.5ML (1.6 MG/ML)	30902030202020	Brand

Approval Criteria

1 - Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID)

Product Name: Revcovi	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVCOVI	ELAPEGADEMASE-LVLR IM SOLN 2.4 MG/1.5ML (1.6 MG/ML)	30902030202020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

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

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160932
Guideline Name	Revlimid (lenalidomide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Revlimid (lenalidomide)
Myelodysplastic Syndromes Indicated for the treatment of adult patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A] **Multiple Myeloma** In combination with dexamethasone is indicated for the treatment of adult patients with multiple myeloma (MM). Also indicated as maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A] **Mantle Cell Lymphoma (MCL)** Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]

Follicular Lymphoma (FL) Revlimid in combination with a rituximab product, is indicated for the treatment of adult patients with previously treated follicular lymphoma (FL). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]

Marginal Zone Lymphoma (MZL) Revlimid in combination with a rituximab product, is indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]

2 . Criteria

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Myelodysplastic Syndromes, Multiple Myeloma, Mantle Cell Lymphoma, Follicular Lymphoma, Marginal Zone Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVLIMID	LENALIDOMIDE CAP 5 MG	99394050000120	Brand
REVLIMID	LENALIDOMIDE CAP 10 MG	99394050000130	Brand
REVLIMID	LENALIDOMIDE CAP 15 MG	99394050000140	Brand
REVLIMID	LENALIDOMIDE CAP 25 MG	99394050000150	Brand
REVLIMID	LENALIDOMIDE CAPS 2.5 MG	99394050000110	Brand
REVLIMID	LENALIDOMIDE CAP 20 MG	99394050000145	Brand
LENALIDOMIDE	LENALIDOMIDE CAP 5 MG	99394050000120	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 10 MG	99394050000130	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 15 MG	99394050000140	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 25 MG	99394050000150	Generic
LENALIDOMIDE	LENALIDOMIDE CAPS 2.5 MG	99394050000110	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 20 MG	99394050000145	Generic

Approval Criteria

1 - Diagnosis of ONE of the following:

1.1 Symptomatic or transfusion-dependent anemia due to myelodysplastic syndrome (MDS) associated with a deletion 5q abnormality [2]

OR

1.2 Multiple Myeloma

OR

1.3 Relapsed or progressed mantle cell lymphoma (MCL)

OR

1.4 Follicular lymphoma (FL) that has been previously treated

OR

1.5 Marginal zone lymphoma (MZL) that has been previously treated

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Myelodysplastic Syndromes, Multiple Myeloma, Mantle Cell Lymphoma, Follicular Lymphoma, Marginal Zone Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
REVLIMID	LENALIDOMIDE CAP 5 MG	99394050000120	Brand

REVLIMID	LENALIDOMIDE CAP 10 MG	99394050000130	Brand
REVLIMID	LENALIDOMIDE CAP 15 MG	99394050000140	Brand
REVLIMID	LENALIDOMIDE CAP 25 MG	99394050000150	Brand
REVLIMID	LENALIDOMIDE CAPS 2.5 MG	99394050000110	Brand
REVLIMID	LENALIDOMIDE CAP 20 MG	99394050000145	Brand
LENALIDOMIDE	LENALIDOMIDE CAP 5 MG	99394050000120	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 10 MG	99394050000130	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 15 MG	99394050000140	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 25 MG	99394050000150	Generic
LENALIDOMIDE	LENALIDOMIDE CAPS 2.5 MG	99394050000110	Generic
LENALIDOMIDE	LENALIDOMIDE CAP 20 MG	99394050000145	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

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 8, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160933
Guideline Name	Riluzole Products - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Exservan (riluzole film), Rilutek (riluzole tablets), Tiglutik (riluzole suspension), Teglutik (riluzole suspension)
Amyotrophic Lateral Sclerosis (ALS) Indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS).

2 . Criteria

Product Name: Brand Rilutek, Teglutik, Tiglutik	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RILUTEK	RILUZOLE TAB 50 MG	74503070000320	Brand
TIGLUTIK	RILUZOLE SUSP 50 MG/10ML	74503070001820	Brand
TEGLUTIK	RILUZOLE SUSP 50 MG/10ML	74503070001820	Brand

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Trial and failure or intolerance to generic riluzole tablets

Product Name: Exservan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
EXSERVAN	RILUZOLE ORAL FILM 50 MG	74503070008220	Brand

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Trial and failure or intolerance to both of the following:

- generic riluzole tablets
- Tiglutik suspension or Teglutik suspension

Product Name: Exservan	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
EXSERVAN	RILUZOLE ORAL FILM 50 MG	74503070008220	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with both of the following formulary alternatives that have the same active ingredients:

- generic riluzole tablets
- Tiglutik suspension or Teglutik suspension

AND

3 - Submission of medical records confirming the formulary alternatives have not been effective and valid clinical rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternatives have not been shown to be effective despite having the same active ingredient

3 . References

1. Rilutek Prescribing Information. Covis Pharma. Zug, Switzerland. March 2020.
2. Tiglutik Prescribing Information. ITF Pharma, Inc. Berwyn, PA. April 2021.
3. Exservan Prescribing Information. Aquestive Therapeutics. Warren, NJ. April 2021.
4. Teglutik Prescribing Information. ITF Pharma, Inc. Berwyn, PA. February 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160934
Guideline Name	Rinvoq (upadacitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rinvoq (upadacitinib) extended-release (ER) tablets
Rheumatoid Arthritis (RA) Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. **Non-radiographic Axial Spondyloarthritis (nr-AxSpA)** Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic

DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

Atopic Dermatitis (AD) Indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Crohn's Disease (CD) Indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.

Drug Name: Rinvoq (upadacitinib) ER tablets, Rinvoq LQ (upadacitinib) oral solution

Psoriatic Arthritis (PsA) Indicated for the treatment of adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq/Rinvoq LQ in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

Polyarticular Juvenile Idiopathic Arthritis (PJIA) Indicated for the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq/Rinvoq LQ in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

2 . Criteria

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq

Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq, Rinvoq LQ	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ LQ	UPADACITINIB ORAL SOLN 1 MG/ML	66603072002020	Brand

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, etanercept)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq/Rinvoq LQ may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq, Rinvoq LQ	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ LQ	UPADACITINIB ORAL SOLN 1 MG/ML	66603072002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq/Rinvoq LQ may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq, Rinvoq LQ	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ LQ	UPADACITINIB ORAL SOLN 1 MG/ML	66603072002020	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq/Rinvoq LQ may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq, Rinvoq LQ	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ LQ	UPADACITINIB ORAL SOLN 1 MG/ML	66603072002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq/Rinvoq LQ may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 6]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 6]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., certolizumab pegol)

AND

6 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 6]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 45 MG	66603072007540	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [7, 8]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [7, 8]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for CD, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Crohn's disease (CD)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 45 MG	66603072007540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 7, 8]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND

2 - Not used in combination with other JAK inhibitors, biological therapies for CD, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand

RINVOQ	UPADACITINIB TAB ER 24HR 45 MG	66603072007540	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [9, 10]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [9, 10]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, golimumab)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 45 MG	66603072007540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 9, 10]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND

2 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhale d corticosteroids, and/or low stable dosages of oral corticosteroids (eq uivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is 12 years of age or older

AND

3 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist

- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

6 - One of the following:

6.1 Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.)

OR

6.2 Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies:

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

AND

7 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RINVOQ	UPADACITINIB TAB ER 24HR 15 MG	66603072007520	Brand
RINVOQ	UPADACITINIB TAB ER 24HR 30 MG	66603072007530	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

AND

2 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [11]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05

	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1

Lower-medium potency	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05

4 . Endnotes

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. [12, 13] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [14]

5 . References

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6 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160935
Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rituxan Hycela (rituximab and hyaluronidase human)
Follicular Lymphoma Indicated for the treatment of adult patients with: 1) Relapsed or refractory, follicular lymphoma as a single agent 2) Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy 3) Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions. **Diffuse Large B-cell Lymphoma** Indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of adult patients with previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC). Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

2 . Criteria

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Diagnosis of follicular lymphoma

AND

2 - One of the following:

2.1 Disease is relapsed or refractory

OR

2.2 Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy

OR

2.3 Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

OR

2.4 Both of the following:

2.4.1 Disease is previously untreated

AND

2.4.2 Medication is used in combination with first-line chemotherapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Diffuse Large B-cell Lymphoma
Approval Length	12 months [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Diagnosis of diffuse large B-cell lymphoma

AND

2 - Disease is previously untreated

AND

3 - Medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy

AND

4 - One of the following:

4.1 Trial and failure, or intolerance to Ruxience

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 months [B]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1400-23400 MG-UNIT/11.7ML	21990002642020	Brand
RITUXAN HYCELA	RITUXIMAB-HYALURONIDASE HUMAN INJ 1600-26800 MG-UNIT/13.4ML	21990002642040	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia

AND

2 - Medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

3 . Endnotes

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

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5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

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]

5 . References

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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-160936
Guideline Name	Roszet (rosuvastatin/ezetimibe) - ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Roszet (rosuvastatin/ezetimibe)
Non-familial hyperlipidemia Indicated as an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C). **Homozygous familial hypercholesterolemia (HoFH)** Indicated alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

2 . Criteria

Product Name: Roszet, Brand Ezetimibe-Rosuvastatin (ST)

Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Brand
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 day supply) or intolerance to one of the following generics:

- rosuvastatin
- atorvastatin 40 mg

- atorvastatin 80 mg

Product Name: Roszet, Brand Ezetimibe-Rosuvastatin (NF)	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Brand
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following diagnoses:

- Non-familial hyperlipidemia
- Homozygous familial hypercholesterolemia (HoFH)

AND

2 - Submission of medical records (e.g., chart notes) documenting history of a trial and failure (of a minimum 30 day supply) or intolerance to two of the following:

- rosuvastatin
- atorvastatin
- simvastatin

AND

3 - Submission of medical records (e.g., chart notes) documenting history of trial and failure (of a minimum 30 day supply) or intolerance to ezetimibe

AND

4 - Physician has provided rationale for needing to use fixed-dose combination therapy with Roszet instead of taking individual products in combination

Product Name: Roszet, Brand Ezetimibe-Rosuvastatin (NF)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Brand
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Brand
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-5 MG	39994002270310	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic

ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-10 MG	39994002270320	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-20 MG	39994002270330	Generic
EZETIMIBE/ROSUVASTATIN	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic
ROSZET	EZETIMIBE-ROSUVASTATIN CALCIUM TAB 10-40 MG	39994002270350	Generic

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy

3 . References

1. Roszet Prescribing Information. Althera Pharmaceuticals LLC. Morristown, NJ. June 2021.
2. 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.
3. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014;35:2146-57.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160937
Guideline Name	Rozlytrek (entrectinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rozlytrek (entrectinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC), as detected by an FDA-approved test. **Solid Tumors** Indicated for the treatment of adult and pediatric patients older than 1 month of age with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion as detected by an FDA-approved test without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

2 . Criteria

Product Name: Rozlytrek	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ROZLYTREK	ENTRECTINIB CAP 100 MG	21533820000120	Brand
ROZLYTREK	ENTRECTINIB CAP 200 MG	21533820000130	Brand
ROZLYTREK	ENTRECTINIB PELLET PACK 50 MG	21533820003020	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Presence of ROS1 rearrangement as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Rozlytrek	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ROZLYTREK	ENTRECTINIB CAP 100 MG	21533820000120	Brand
ROZLYTREK	ENTRECTINIB CAP 200 MG	21533820000130	Brand
ROZLYTREK	ENTRECTINIB PELLET PACK 50 MG	21533820003020	Brand

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Presence of neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.) as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [A]

AND

3 - No known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions) [2]

AND

4 - Disease is one of the following:

- Metastatic
- Unresectable (including cases where surgical resection is likely to result in severe morbidity)

AND

5 - One of the following:

- Disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) [3]
- Disease has no satisfactory alternative treatments

Product Name: Rozlytrek	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Solid Tumors

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ROZLYTREK	ENTRECTINIB CAP 100 MG	21533820000120	Brand
ROZLYTREK	ENTRECTINIB CAP 200 MG	21533820000130	Brand
ROZLYTREK	ENTRECTINIB PELLET PACK 50 MG	21533820003020	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. The most common cancers listed in the pivotal trials which evaluated the efficacy of Rozlytrek were: sarcoma, lung, salivary gland tumors, breast, thyroid and colorectal cancer. [1]

4 . References

1. Rozlytrek Prescribing Information. Genentech USA, Inc. South San Francisco, CA. January 2024
2. Drilon A, Nagasubramanian R, Blake JF, et al. A next-generation TRK kinase inhibitor overcomes acquired resistance to prior TRK kinase inhibition in patients with TRK fusion-positive solid tumors. Cancer Discov. 2017 Sep;7(9):963-972.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160938
Guideline Name	Rydapt (midostaurin)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Rydapt (midostaurin) capsules
Acute Myeloid Leukemia Indicated for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Limitations of Use: Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML. **Aggressive Systemic Mastocytosis, Systemic Mastocytosis with Associated Hematological Neoplasm, or Mast Cell Leukemia** Indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

2 . Criteria

Product Name: Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 Month [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYDAPT	MIDOSTAURIN CAP 25 MG	21533030000130	Brand

Approval Criteria

1 - Diagnosis of newly diagnosed acute myeloid leukemia (AML)

AND

2 - FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [5]

AND

3 - Used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation

Product Name: Rydapt	
Diagnosis	Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), and Mast Cell Leukemia (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

RYDAPT	MIDOSTAURIN CAP 25 MG	21533030000130	Brand

Approval Criteria

1 - One of the following diagnoses: [4]

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with associated hematological neoplasm (SM-AHN)
- Mast cell leukemia (MCL)

Product Name: Rydapt	
Diagnosis	All Indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RYDAPT	MIDOSTAURIN CAP 25 MG	21533030000130	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

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

1. Rydapt Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. May 2023.

2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.1.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed February 27, 2023.
3. Stone RM, Mandrekar S, Sanford BL, et al. The multi-kinase inhibitor midostaurin (M) prolongs survival compared with placebo (P) in combination with daunorubicin (D)/cytarabine (C) induction (ind), high-dose c consolidation (consol), and as maintenance (maint) therapy in newly diagnosed acute myeloid leukemia (AML) patients (pts) age 18-60 with FLT3 Mutations (muts): an international prospective randomized (rand) p-controlled double-blind trial (CALGB 10603/RATIFY [Alliance]). Blood. 2015 Dec;126:6.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Systemic mastocytosis v.2.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf. Accessed February 27, 2023.
5. U.S. Food and Drug Administration: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools. Accessed December13, 2019.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160939
Guideline Name	Sapropterin Products
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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

1. Kuvan prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. August 2024.
2. Levy HL, Milanowski A, Chakrapani A, et al. Efficacy of sapropterin dihydrochloride (tetrahydrobiopterin, 6R-BH4) for reduction of phenylalanine concentration in patients with phenylketonuria: a phase III randomised placebo-controlled study. Lancet. 2007;370(9586):504-10.
3. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014 Feb;16(2):188-200.
4. Javygtor prescribing information. Dr. Reddys Laboratories Inc. Princeton, NJ. May 2022.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-158855
Guideline Name	Savella
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Savella (milnacipran)
Fibromyalgia Indicated for the management of fibromyalgia. Savella is not approved for use in pediatric patients.

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.

Prior Authorization Guideline

Guideline ID	GL-160940
Guideline Name	Selzentry (maraviroc)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 adults 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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160941
Guideline Name	Sensipar (cinacalcet)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sensipar (cinacalcet)
Secondary Hyperparathyroidism Indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis. Limitations of Use: Sensipar is not indicated for use in adult patients with CKD who are not on dialysis because of an increased risk of hypocalcemia. **Parathyroid Carcinoma** Indicated for the treatment of hypercalcemia in adult patients with parathyroid carcinoma. **Primary Hyperparathyroidism** Indicated for the treatment of hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

2 . Criteria

Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	Secondary hyperparathyroidism [1-3]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SENSIPAR	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Brand
SENSIPAR	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Brand
SENSIPAR	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Brand
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Generic

Approval Criteria

1 - Patient is 18 years of age or older [1, A]

AND

2 - Diagnosis of secondary hyperparathyroidism with chronic kidney disease on dialysis

AND

3 - Trial and failure, contraindication or intolerance to both of the following:

- A phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.)
- A vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.)

AND

4 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)

AND

5 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	Hypercalcemia with parathyroid carcinoma
Approval Length	12 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SENSIPAR	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Brand
SENSIPAR	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Brand
SENSIPAR	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Brand
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Generic

Approval Criteria

1 - Patient is 18 years of age or older [1, A]

AND

2 - Diagnosis of hypercalcemia with parathyroid carcinoma

AND

3 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)

AND

4 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	Severe hypercalcemia with primary hyperparathyroidism [4-5]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SENSIPAR	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Brand
SENSIPAR	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Brand
SENSIPAR	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Brand
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Generic

Approval Criteria

1 - Patient is 18 years of age or older [1, A]

AND

2 - Diagnosis of severe hypercalcemia (level greater than 1 mg/dL above the upper limit of normal) with primary hyperparathyroidism [C, D]

AND

3 - Patient is unable to undergo parathyroidectomy

AND

4 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)

AND

5 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	All diagnoses listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SENSIPAR	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Brand
SENSIPAR	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Brand
SENSIPAR	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Brand
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 30 MG (BASE EQUIV)	30905225100320	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 60 MG (BASE EQUIV)	30905225100330	Generic
CINACALCET HYDROCHLORIDE	CINACALCET HCL TAB 90 MG (BASE EQUIV)	30905225100340	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. Sensipar is not indicated for use in pediatric patients. In aggregate, pediatric clinical studies did not establish a safe and effective Sensipar dosing regimen for the pediatric

population. Dosing with Sensipar in Pediatric Study 1 was stopped because of a fatality in a Sensipar-treated individual. The individual was noted to be severely hypocalcemic at the time of death. [1]

B. In the pivotal study of Sensipar for parathyroid carcinoma, patients were treated with maintenance therapy for up to 48 weeks. [1]
C. As recommended by an endocrinologist consultant, hypercalcemia is defined as serum calcium level greater than or equal to 12.5 mg/dL. [5]
D. In the pivotal study of Sensipar for primary hyperparathyroidism, severe hypercalcemia was defined as a screening serum calcium level of > 12.5 mg/dL. The median exposure to Sensipar was 270 days (range: 32-1,105 days). [1]

4 . References

1. Sensipar prescribing information. Amgen Inc. Thousand Oaks, CA. December 2019.
2. Block GA, Martin KJ, de Francisco AL, et al. Cinacalcet for secondary hyperparathyroidism in patients receiving hemodialysis. N Engl J Med. 2004;350(15):1516-25.
3. Lindberg JS, Culleton B, Wong G, et al. Cinacalcet HCl, an oral calcimimetic agent for the treatment of secondary hyperparathyroidism in hemodialysis and peritoneal dialysis: a randomized, double-blind, multicenter study. J Am Soc Nephrol. 2005;16(3):800-7.
4. Peacock M, Bilezikian JP, Klassen PS, et al. Cinacalcet hydrochloride maintains long-term normocalcemia in patients with primary hyperparathyroidism. J Clin Endocrinol Metab. 2005;90(1):135-41.
5. Per clinical consult with endocrinologist, July 5, 2011.
6. Cinacalcet Prescribing Information. Actavis Pharma, Inc. Parsippany, NJ. August 2018.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160942
Guideline Name	SGLT2 Inhibitors - ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Brenzavvy (bexagliflozin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Brenzavvy is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.

Drug Name: Invokamet (canagliflozin/metformin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Canagliflozin is indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.

Drug Name: Invokamet XR (canagliflozin/metformin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Canagliflozin is indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.
Drug Name: Invokana (canagliflozin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of use: Invokana is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. Not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m 2. INVOKANA is likely to be ineffective in this setting based upon its mechanism of action.
Drug Name: Qtern (dapagliflozin and saxagliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: QTERN is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus
Drug Name: Segluromet (ertugliflozin and metformin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.
Drug Name: Steglatro (ertugliflozin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus
Drug Name: Steglujan (ertugliflozin and sitagliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. Has not been studied in patients

with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using STEGLUJAN.
Drug Name: Inpefa
Heart failure or Type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors Indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with: 1) heart failure, or 2) type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

2 . Criteria

Product Name: Brand Bexagliflozin, Brenzavvy, Qtern, Segluromet, Steglatro, Steglujan, Invokamet, Invokamet XR, Invokana	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
INVOKANA	CANAGLIFLOZIN TAB 100 MG	27700020000320	Brand
INVOKANA	CANAGLIFLOZIN TAB 300 MG	27700020000330	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 50-500 MG	27996002200320	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 50-1000 MG	27996002200330	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 150-500 MG	27996002200340	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 150-1000 MG	27996002200350	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 50-500 MG	27996002207520	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 50-1000 MG	27996002207530	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 150-500 MG	27996002207540	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 150-1000 MG	27996002207550	Brand
QTERN	DAPAGLIFLOZIN-SAXAGLIPTIN TAB 10-5 MG	27996502200330	Brand
STEGLATRO	ERTUGLIFLOZIN L-PYROGLUTAMIC ACID TAB 5 MG (BASE EQUIV)	27700055200320	Brand

STEGLATRO	ERTUGLIFLOZIN L-PYROGLUTAMIC ACID TAB 15 MG (BASE EQUIV)	27700055200340	Brand
STEGLUJAN	ERTUGLIFLOZIN-SITAGLIPTIN TAB 5-100 MG	27996502350320	Brand
STEGLUJAN	ERTUGLIFLOZIN-SITAGLIPTIN TAB 15-100 MG	27996502350330	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 2.5-500 MG	27996002450310	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 2.5-1000 MG	27996002450320	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 7.5-500 MG	27996002450330	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 7.5-1000 MG	27996002450340	Brand
QTERN	DAPAGLIFLOZIN-SAXAGLIPTIN TAB 5-5 MG	27996502200320	Brand
BRENZAVVY	BEXAGLIFLOZIN TAB 20 MG	27700010000320	Brand
BEXAGLIFLOZIN	BEXAGLIFLOZIN TAB 20 MG	27700010000320	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

2.2 Patient has one of the following (Applies to Invokamet, Invokamet XR, and Invokana only):

- History of atherosclerotic cardiovascular disease (ASCVD)
- High risk for ASCVD with multiple risk factors (e.g., obesity, hypertension, smoking, dyslipidemia, albuminuria)
- Established chronic kidney disease (CKD)
- Heart failure

AND

3 - Trial and failure of a minimum 90 day supply, or intolerance to any one of the following preferred brands:

- Farxiga
- Xigduo XR

AND

4 - Trial and failure of a minimum 90 day supply, or intolerance to one of the following:

- Glyxambi
- Jardiance
- Synjardy
- Synjardy XR
- Trijardy XR

Product Name: Inpefa	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
INPEFA	SOTAGLIFLOZIN TAB 200 MG	40750010000320	Brand
INPEFA	SOTAGLIFLOZIN TAB 400 MG	40750010000340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 90 day supply, contraindication, or intolerance to both of the following:

- Farxiga
- Jardiance

Product Name: Brand Bexagliflozin, Brenzavvy, Qtern, Segluromet, Steglatro, Steglujan, Invokamet, Invokamet XR, Invokana	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
INVOKANA	CANAGLIFLOZIN TAB 100 MG	27700020000320	Brand
INVOKANA	CANAGLIFLOZIN TAB 300 MG	27700020000330	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 50-500 MG	27996002200320	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 50-1000 MG	27996002200330	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 150-500 MG	27996002200340	Brand
INVOKAMET	CANAGLIFLOZIN-METFORMIN HCL TAB 150-1000 MG	27996002200350	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 50-500 MG	27996002207520	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 50-1000 MG	27996002207530	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 150-500 MG	27996002207540	Brand
INVOKAMET XR	CANAGLIFLOZIN-METFORMIN HCL TAB SR 24HR 150-1000 MG	27996002207550	Brand
QTERN	DAPAGLIFLOZIN-SAXAGLIPTIN TAB 10-5 MG	27996502200330	Brand
STEGLATRO	ERTUGLIFLOZIN L-PYROGLUTAMIC ACID TAB 5 MG (BASE EQUIV)	27700055200320	Brand
STEGLATRO	ERTUGLIFLOZIN L-PYROGLUTAMIC ACID TAB 15 MG (BASE EQUIV)	27700055200340	Brand
STEGLUJAN	ERTUGLIFLOZIN-SITAGLIPTIN TAB 5-100 MG	27996502350320	Brand

STEGLUJAN	ERTUGLIFLOZIN-SITAGLIPTIN TAB 15-100 MG	27996502350330	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 2.5-500 MG	27996002450310	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 2.5-1000 MG	27996002450320	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 7.5-500 MG	27996002450330	Brand
SEGLUROMET	ERTUGLIFLOZIN-METFORMIN HCL TAB 7.5-1000 MG	27996002450340	Brand
QTERN	DAPAGLIFLOZIN-SAXAGLIPTIN TAB 5-5 MG	27996502200320	Brand
BRENZAVVY	BEXAGLIFLOZIN TAB 20 MG	27700010000320	Brand
BEXAGLIFLOZIN	BEXAGLIFLOZIN TAB 20 MG	27700010000320	Generic

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Submission of medical records (e.g., chart notes) or paid claims confirming one of the following:

2.1 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

2.2 Patient has one of the following (Applies to Invokamet, Invokamet XR, and Invokana only):

- History of atherosclerotic cardiovascular disease (ASCVD)
- High risk for ASCVD with multiple risk factors (e.g., obesity, hypertension, smoking, dyslipidemia, albuminuria)

- Established chronic kidney disease (CKD)
- Heart failure

AND

3 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure of a minimum 90 day supply, or intolerance to any one of the following preferred brands:

- Farxiga
- Xigduo XR

AND

4 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure of a minimum 90 day supply, or intolerance to one of the following:

- Glyxambi
- Jardiance
- Synjardy
- Synjardy XR
- Trijardy XR

Product Name: Inpefa	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
INPEFA	SOTAGLIFLOZIN TAB 200 MG	40750010000320	Brand
INPEFA	SOTAGLIFLOZIN TAB 400 MG	40750010000340	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Submission of medical records (e.g., chart notes) or piad claims confirming trial and failure of a minimum 90 day supply, contraindication, or intolerance to both of the following:

- Farxiga
- Jardiance

3 . References

1. Invokana Prescribing Information. Janssen. Titusville, NJ. July 2023.
2. Invokamet Prescribing Information. Janssen. Titusville, NJ. January 2024.
3. Invokamet XR Prescribing information. Janssen Ortho, LLC. Titusville, NJ. January 2024.
4. Qtern Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. September 2023.
5. Segluromet Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. June 2024.
6. Steglatro Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. June 2024.
7. Steglujan Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. June 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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160943
Guideline Name	Short-Acting Bronchodilators
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Proventil HFA (albuterol sulfate inhalation aerosol)
Bronchospasm Indicated in adults and children 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.
Drug Name: Xopenex HFA (levalbuterol tartrate inhalation aerosol)
Bronchospasm Indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.
Drug Name: Ventolin HFA, Proair HFA (albuterol sulfate inhalation aerosol), Proair Digihaler (albuterol sulfate inhalation powder), Proair Respiclick (albuterol sulfate powder)
Bronchospasm Indicated for the treatment of or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.

Exercise-Induced Bronchospasm Indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

2 . Criteria

Product Name: Proair Digihaler, Proair HFA, Proair Respiclick, Proventil HFA, Xopenex HFA, levalbuterol HFA, Ventolin HFA or Brand Albuterol HFA (Prasco manufacturer only, NDC 66993-0019-68)

Approval Length	12 Months
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
PROVENTIL HFA	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT (90MCG BASE EQUIV)	44201010103410	Brand
XOPENEX HFA	LEVALBUTEROL TARTRATE INHAL AEROSOL 45 MCG/ACT (BASE EQUIV)	44201045503220	Brand
XOPENEX HFA	LEVALBUTEROL TARTRATE INHAL AEROSOL 45 MCG/ACT (BASE EQUIV)	44201045503220	Generic
LEVALBUTEROL TARTRATE HFA	LEVALBUTEROL TARTRATE INHAL AEROSOL 45 MCG/ACT (BASE EQUIV)	44201045503220	Generic
PROVENTIL HFA	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT (90MCG BASE EQUIV)	44201010103410	Generic
VENTOLIN HFA	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT (90MCG BASE EQUIV)	44201010103410	Generic
PROAIR HFA	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT (90MCG BASE EQUIV)	44201010103410	Generic
PROAIR RESPICLICK	ALBUTEROL SULFATE AER POW BA 108 MCG/ACT (90 MCG BASE EQUIV)	44201010108020	Brand
ALBUTEROL SULFATE HFA	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT (90MCG BASE EQUIV)	44201010103410	Generic
PROAIR DIGIHALER	ALBUTEROL SULFATE AER POW BA 108 MCG/ACT WITH SENSOR	44201010128020	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial (of a minimum 30-day supply) of generic albuterol HFA

3 . References

1. Proventil HFA [prescribing information]. Whitehouse Station, NJ: Merck & Co. Inc; October 2019.
2. Xopenex HFA [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; November 2023.
3. Ventolin HFA [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.
4. Proair HFA [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.
5. Proair Digihaler [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; February 2024.
6. Proair Respiclick [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160944
Guideline Name	Signifor, Signifor LAR (pasireotide) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 - 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. Lebanon, NJ. July 2020.
2. Signifor Prescribing Information. Recordati Rare Diseases Inc. Lebanon, NJ . March 2020.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160945
Guideline Name	Simponi, Simponi Aria (golimumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-158788
Guideline Name	Skin Cancer Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Klisyri (tirbanibulin) ointment
Actinic Keratosis indicated for the topical treatment of actinic keratosis on the face or scalp.

2 . Criteria

Product Name: Klisyri	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
KLISYRI	TIRBANIBULIN OINTMENT 1%	90374580004220	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to both of the following generics:

- fluorouracil
- imiquimod

3 . References

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. Klisyri Prescribing Information. Almirall, LLC. Exton, PA. November 2023.

Prior Authorization Guideline

Guideline ID	GL-160946
Guideline Name	Skyclarys (omaveloxolone)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Skyclarys (omaveloxolone)
Friedreich's ataxia Indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

2 . Criteria

Product Name: Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYCLARYS	OMAVELOXOLONE CAP 50 MG	74135060000120	Brand

Approval Criteria

1 - Diagnosis of Friedreich's ataxia confirmed via genetic testing demonstrating mutation in the FXN gene

AND

2 - Patient is 16 years of age or older

AND

3 - Patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of greater than or equal to 20 and less than or equal to 80

AND

4 - Patient has a B-type natriuretic peptide value less than or equal to 200 pg/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Neurologist
- Neurogeneticist
- Physiatrist (Physical Medicine and Rehabilitation Specialist)

Product Name: Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYCLARYS	OMAVELOXOLONE CAP 50 MG	74135060000120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of less than or equal to 80 [A]

3 . Endnotes

A. Patients enrolled in the trial were those with an mFARS score between 20 and 80. There is no evidence of benefit for patients with severe neurologic dysfunction with an mFARS score of greater than 80.

4 . References

1. Skyclarys Prescribing Information. Reata Pharmaceuticals, Inc. Cambridge, MA. January 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160947
Guideline Name	Skyrizi (risankizumab-rzaa)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Skyrizi SC (risankizumab-rzaa)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of active psoriatic arthritis in adults. **Crohn's Disease (CD)** Indicated for the treatment of moderately to severely active Crohn's disease in adults. **Ulcerative Colitis (UC)** Indicated for the treatment of moderately to severely active ulcerative colitis in adults.
Drug Name: Skyrizi IV (risankizumab-rzaa)
Crohn's Disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adults.

2 . Criteria

Product Name: Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI PEN	RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150 MG/ML	9025057070D520	Brand
SKYRIZI	RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150 MG/ML	9025057070E540	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI PEN	RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150 MG/ML	9025057070D520	Brand
SKYRIZI	RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150 MG/ML	9025057070E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI PEN	RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150 MG/ML	9025057070D520	Brand
SKYRIZI	RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150 MG/ML	9025057070E540	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI PEN	RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150 MG/ML	9025057070D520	Brand
SKYRIZI	RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150 MG/ML	9025057070E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI	RISANKIZUMAB-RZAA IV SOLN 600 MG/10ML (60 MG/ML)	52504060702020	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - One of the following [5, 6]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss

- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [5, 6]:

- 6-mercaptopurine
- Azathioprine
- Methotrexate
- Corticosteroid (e.g., prednisone)

AND

4 - Will be administered as an intravenous induction dose

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name: Skyrizi SC 180 mg, 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 180 MG/1.2ML	5250406070E210	Brand
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 360 MG/2.4ML	5250406070E220	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi IV	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI	RISANKIZUMAB-RZAA IV SOLN 600 MG/10ML (60 MG/ML)	52504060702020	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein)

- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [7, 8]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroid (e.g., prednisone)
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

AND

4 - Will be administered as an intravenous induction dose

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name: Skyrizi SC 180 mg, 360 mg	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 180 MG/1.2ML	5250406070E210	Brand
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 360 MG/2.4ML	5250406070E220	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Skyrizi SC 180 mg, 360 mg	
Diagnosis	Crohn's Disease (CD), Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 180 MG/1.2ML	5250406070E210	Brand
SKYRIZI	RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN CARTRIDGE 360 MG/2.4ML	5250406070E220	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5-8]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Notes	If patient meets criteria above, please approve at GPI-14

3 . References

1. Skyrizi Prescribing Information. AbbVie, Inc. North Chicago, IL. June 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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160948
Guideline Name	Soliris (eculizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Soliris (eculizumab)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. **Atypical Hemolytic Uremic Syndrome (aHUS)** Indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. Limitations of Use: Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). **Generalized Myasthenia Gravis (gMG)** Indicated for the treatment of adult patients with generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody positive. **Neuromyelitis Optica Spectrum Disorder (NMOSD)** Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name: Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

Product Name: Soliris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS)

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist
- Nephrologist

Product Name: Soliris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response (e.g., increase in mean platelet counts, hematologic normalization) to therapy

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

Product Name: Soliris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - Trial and failure, contraindication, or intolerance to one of the following:

- Ultomiris (ravulizumab)
- Vyvgart (efgartigimod)

AND

4 - One of the following: [2, 3]

4.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

4.2 Both of the following:

4.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

4.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)

- Intravenous immunoglobulin (IVIG)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Soliris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and failure, contraindication, or intolerance to one of the following:

- Ultomiris (ravulizumab)
- Vyvgart (efgartigimod)

Product Name: Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Ophthalmologist

Product Name: Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOLIRIS	ECULIZUMAB IV SOLN 300 MG/30ML (10 MG/ML) (FOR INFUSION)	85805050002020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Soliris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. November 2020.
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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160949
Guideline Name	Somavert (pegvisomant)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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-I (IGF-I) 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. August 2021.
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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160950
Guideline Name	Sovaldi (sofosbuvir)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sovaldi (sofosbuvir)
Chronic Hepatitis C (CHC) ADULT PATIENTS: Indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen. - Genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin. - Genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin. PEDIATRIC PATIENTS: Indicated for the treatment of chronic HCV genotype 2 or 3 infection in pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

2 . Criteria

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1 or 4 - Sovaldi Plus Peginterferon Plus Ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOVALDI	SOFOSBUVIR TAB 200 MG	12353080000310	Brand
SOVALDI	SOFOSBUVIR TAB 400 MG	12353080000320	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 150 MG	12353080003015	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 200 MG	12353080003020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1 or 4

AND

2 - Used in combination with peginterferon alfa and ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2 - Sovaldi Plus Ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOVALDI	SOFOSBUVIR TAB 200 MG	12353080000310	Brand
SOVALDI	SOFOSBUVIR TAB 400 MG	12353080000320	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 150 MG	12353080003015	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 200 MG	12353080003020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 2 infection

AND

2 - Used in combination with ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Epclusa (sofosbuvir/velpatasvir)

- Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 3 - Sovaldi Plus Ribavirin
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOVALDI	SOFOSBUVIR TAB 200 MG	12353080000310	Brand
SOVALDI	SOFOSBUVIR TAB 400 MG	12353080000320	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 150 MG	12353080003015	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 200 MG	12353080003020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 3 infection

AND

2 - Used in combination with ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Mavyret)
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SOVALDI	SOFOSBUVIR TAB 200 MG	12353080000310	Brand
SOVALDI	SOFOSBUVIR TAB 400 MG	12353080000320	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 150 MG	12353080003015	Brand

SOVALDI	SOFOSBUVIR PELLET PACK 200 MG	12353080003020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Mavyret (glecaprevir/pibrentasvir) [2]

AND

3 - Used in combination with Mavyret (glecaprevir/pibrentasvir) and ribavirin [2]

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Vosevi)
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

SOVALDI	SOFOSBUVIR TAB 200 MG	12353080000310	Brand
SOVALDI	SOFOSBUVIR TAB 400 MG	12353080000320	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 150 MG	12353080003015	Brand
SOVALDI	SOFOSBUVIR PELLET PACK 200 MG	12353080003020	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [2]

AND

3 - Used in combination with Mavyret (glecaprevir/pibrentasvir) and ribavirin [2]

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

3 . References

1. Sovaldi Prescribing Information. Gilead Sciences, Inc. Foster City, CA. March 2020.

2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160951
Guideline Name	Spevigo (spesolimab-sbzo)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Spevigo (spesolimab-sbzo)
Generalized Pustular Psoriasis (GPP) Indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.

2 . Criteria

Product Name: Spevigo IV	
Approval Length	14 Days [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPEVIGO	SPESOLIMAB-SBZO IV SOLN 450 MG/7.5ML (60 MG/ML)	90250577702050	Brand

Approval Criteria

1 - Diagnosis of generalized pustular psoriasis (GPP)

AND

2 - Patient has a moderate to severe GPP flare based on one of the following:

- Presence of fresh pustules (new appearance or worsening of pustules)
- At least 5% of body surface area (BSA) covered with erythema and the presence of pustules
- A Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) [B]
- GPPPGA pustulation sub score of at least 2 (mild)

AND

3 - Both of the following:

- Patient is 12 years of age or older
- Patient weighs at least 40kg

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Patient has not already received two infusions of Spevigo for a single flare

Product Name: Spevigo SC

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPEVIGO	SPESOLIMAB-SBZO SUBCUTANEOUS SOLN PREF SYR 150 MG/ML	9025057770E530	Brand

Approval Criteria

1 - Diagnosis of generalized pustular psoriasis (GPP) as defined by both of the following [2]:

- Primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques)
- Disease is relapsing (>1 episode) or persistent (>3 months)

AND

2 - Subcutaneous formulation will not be used to treat GPP flare

AND

3 - Both of the following:

- Patient is 12 years of age or older
- Patient weighs at least 40kg

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Spevigo SC	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SPEVIGO	SPESOLIMAB-SBZO SUBCUTANEOUS SOLN PREF SYR 150 MG/ML	9025057770E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in number of flares)

3 . Endnotes

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.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160952
Guideline Name	Sprycel (dasatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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)

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)

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; February 2023.

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160953
Guideline Name	State Mandate Reference Document
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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 - For Iowa, (effective 1/1/2018), 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 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. Step therapy requirements 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. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160954
Guideline Name	Stelara (ustekinumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Stelara SC (ustekinumab)
Plaque Psoriasis (PsO) Indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of patients 6 years or older with active psoriatic arthritis. **Crohn's Disease (CD)** Indicated for the treatment of adult patients with moderately to severely active Crohn's disease. **Ulcerative Colitis (UC)** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.
Drug Name: Stelara IV (ustekinumab)
Crohn's Disease (CD) Indicated for the treatment of adult patients with moderately to severely active Crohn's disease.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

2 . Criteria

Product Name: Stelara SC 45 mg/0.5 mL	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

5 - Prescribed by or in consultation with a dermatologist

Product Name: Stelara SC 90 mg/1 mL	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis

- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient's weight is greater than 100 kg (220 lbs)

AND

4 - Patient is 6 years of age or older

AND

5 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

6 - Prescribed by or in consultation with a dermatologist

Product Name: Stelara SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand

STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Stelara SC 45 mg/0.5 mL	
Diagnosis	Psoriatic arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Stelara SC 90 mg/1 mL	
Diagnosis	Psoriatic arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Diagnosis of co-existent moderate to severe psoriasis [1, 4]

AND

4 - Patient's weight is greater than 100 kg (220 lbs)

AND

5 - Patient is 6 years of age or older

AND

6 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Stelara SC	
Diagnosis	Psoriatic arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Stelara IV	
Diagnosis	Crohn's Disease
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INFUSION)	52504070002020	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [5, 6]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [5, 6]:

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - Stelara is to be administered as an intravenous induction dose

AND

5 - Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's disease:

- 260 mg for patients weighing 55 kg or less
- 390 mg for patients weighing more than 55 kg to 85 kg
- 520 mg for patients weighing more than 85 kg

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara SC	
Diagnosis	Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Will be used as a maintenance dose following the intravenous induction dose

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara IV	
Diagnosis	Ulcerative Colitis
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB IV SOLN 130 MG/26ML (5 MG/ML) (FOR IV INFUSION)	52504070002020	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers

- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [7, 8]:

- Corticosteroid (e.g., prednisone)
- 6-mercaptopurine
- Azathioprine
- Aminosalicylates (e.g., mesalamine, olsalazine, sulfasalazine)

AND

4 - Stelara is to be administered as an intravenous induction dose

AND

5 - Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for ulcerative colitis:

- 260 mg for patients weighing 55 kg or less
- 390 mg for patients weighing more than 55 kg to 85 kg
- 520 mg for patients weighing more than 85 kg

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara SC	
Diagnosis	Ulcerative Colitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Will be used as a maintenance dose following the intravenous induction dose

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara SC	
Diagnosis	Crohn's Disease and Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STELARA	USTEKINUMAB INJ 45 MG/0.5ML	90250585002020	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 45 MG/0.5ML	9025058500E520	Brand
STELARA	USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML	9025058500E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5-8]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

3 . References

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160955
Guideline Name	Stivarga (regorafenib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Stivarga (regorafenib)
Metastatic Colorectal Cancer (mCRC) Indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild- type, an anti-EGFR therapy. **Gastrointestinal Stromal Tumor (GIST)** Indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate. **Hepatocellular Carcinoma (HCC)** Indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

2 . Criteria

Product Name: Stivarga	
Diagnosis	Metastatic Colorectal Cancer (mCRC) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STIVARGA	REGORAFENIB TAB 40 MG	21533050000320	Brand

Approval Criteria

1 - Diagnosis of metastatic colorectal cancer (mCRC)

Product Name: Stivarga	
Diagnosis	Gastrointestinal Stromal Tumor (GIST) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STIVARGA	REGORAFENIB TAB 40 MG	21533050000320	Brand

Approval Criteria

1 - Diagnosis of Gastrointestinal Stromal Tumor (GIST)

AND

2 - Disease is one of the following:

- Locally advanced

- Unresectable
- Metastatic

Product Name: Stivarga	
Diagnosis	Hepatocellular Carcinoma (HCC) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STIVARGA	REGORAFENIB TAB 40 MG	21533050000320	Brand

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma (HCC)

Product Name: Stivarga	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
STIVARGA	REGORAFENIB TAB 40 MG	21533050000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Stivarga Prescribing Information. Bayer HealthCare Pharmaceuticals Inc., December 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 19, 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160956
Guideline Name	Sucraid (sacrosidase) Oral Solution
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sucraid (sacrosidase) Oral Solution
Congenital Sucrase-Isomaltase Deficiency (CSID) Indicated as oral replacement therapy of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

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 - 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. May 2022.
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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160957
Guideline Name	Sunosi (solriamfetol)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sunosi (solriamfetol)
Narcolepsy Indicated to improve wakefulness in adults patients with excessive daytime sleepiness associated with narcolepsy. **Obstructive sleep apnea (OSA)** Indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with obstructive sleep apnea (OSA). Limitations of use: Sunosi is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating Sunosi for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi. Sunosi is not a substitute for these modalities.

2 . Criteria

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUNOSI	SOLRIAMFETOL HCL TAB 75 MG (BASE EQUIV)	61370070200320	Brand
SUNOSI	SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV)	61370070200340	Brand

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [A, B]

AND

2 - BOTH of the following;

2.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- generic modafinil
- generic armodafinil

AND

2.2 ONE of the following:

2.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

2.2.2 History of or potential for a substance use disorder

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUNOSI	SOLRIAMFETOL HCL TAB 75 MG (BASE EQUIV)	61370070200320	Brand
SUNOSI	SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV)	61370070200340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUNOSI	SOLRIAMFETOL HCL TAB 75 MG (BASE EQUIV)	61370070200320	Brand
SUNOSI	SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV)	61370070200340	Brand

Approval Criteria

1 - Diagnosis of obstructive sleep apnea defined by one of the following: [4]

1.1 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [C]

OR

1.2 Both of the following:

1.2.1 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [C]

AND

1.2.2 One of the following signs/symptoms are present:

- Daytime sleepiness
- Nonrestorative sleep
- Fatigue
- Insomnia
- Waking up with breath holding, gasping, or choking
- Habitual snoring noted by a bed partner or other observer
- Observed apnea

AND

2 - Both of the following:

2.1 Standard treatment(s) for the underlying obstruction (e.g., with continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

3 - Trial and failure, contraindication or intolerance to ONE of the following:

- generic modafinil
- generic armodafinil

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUNOSI	SOLRIAMFETOL HCL TAB 75 MG (BASE EQUIV)	61370070200320	Brand
SUNOSI	SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV)	61370070200340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

AND

2 - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP)

3 . Endnotes

A. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 1 (narcolepsy with cataplexy) require: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) The presence of one or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT; or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than or equal to 110 pg/mL or less than one-third of mean values obtained in normal subjects with the same standardized assay) [2,3].

B. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 2 (narcolepsy without cataplexy) include: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) Cataplexy is absent. 3) CSF hypocretin-1 levels, if measured, is either greater than 100 pg/mL or greater than one-third of mean values obtained in normal subjects with the same standardized assay. 4) A mean sleep latency of less than or

equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT. 5) Hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal [2,3].

C. Examples of obstructive respiratory events include: obstructive and mixed apneas, hypopneas, or respiratory effort related arousals (RERA) [2].

4 . References

1. Sunosi Prescribing Information. Jazz Pharmaceuticals, Inc. Palo Alto, CA. October 2021.
2. Sateia MJ. International classification of sleep disorders - third edition: highlights and modifications. CHEST. 2014 Nov;146(5):1387-1394.
3. UpToDate. Clinical features and diagnosis of narcolepsy. Available by subscription at: https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-narcolepsy-in-adults?search=Clinical%20features%20and%20diagnosis%20of%20narcolepsy&source=search_result&selectedTitle=1~116&usage_type=default&display_rank=1. Accessed March 30, 2020.
4. UpToDate. Clinical presentation and diagnosis of obstructive sleep apnea in adults. Available by subscription at: https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-obstructive-sleep-apnea-in-adults?search=obstructive%20sleep%20apnea&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4. Accessed March 30, 2020.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160958
Guideline Name	Sutent (sunitinib) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Sutent (sunitinib)
Gastrointestinal stromal tumor (GIST) Indicated for the treatment of adult patients with gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate. **Advanced pancreatic neuroendocrine tumors (pNET)** Indicated for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in adult patients with unresectable locally advanced or metastatic disease. **Advanced renal cell carcinoma** Indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC). **Adjuvant treatment of renal cell carcinoma** Indicated for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy.

2 . Criteria

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - History of disease progression, contraindication, or intolerance to Gleevec (imatinib)

AND

3 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name: Brand Sutent	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming history of disease progression, contraindication, or intolerance to Gleevec (imatinib)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand

SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET)

AND

2 - One of the following:

- unresectable locally advanced disease
- metastatic disease

AND

3 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand

SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name: Brand Sutent	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand

Approval Criteria

1 - Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET)

AND

2 - One of the following:

- unresectable locally advanced disease
- metastatic disease

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Diagnosis of advanced/metastatic renal cell carcinoma

AND

2 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name: Brand Sutent	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand

Approval Criteria

1 - Diagnosis of advanced/metastatic renal cell carcinoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Adjuvant Treatment of Renal Cell Carcinoma
Approval Length	12 Months [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand
SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand

SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand
SUNITINIB MALATE	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Generic
SUNITINIB MALATE	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Generic

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - Used as adjuvant therapy

AND

3 - Patient is at high risk of recurrent RCC following nephrectomy

AND

4 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name: Brand Sutent	
Diagnosis	Adjuvant Treatment of Renal Cell Carcinoma
Approval Length	12 Months [A]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
SUTENT	SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)	21533070300120	Brand

SUTENT	SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)	21533070300130	Brand
SUTENT	SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)	21533070300140	Brand
SUTENT	SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)	21533070300135	Brand

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - Used as adjuvant therapy

AND

3 - Patient is at high risk of recurrent RCC following nephrectomy

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

3 . Endnotes

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
11/19/2024	Bulk Copy. CM 11.19.24

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-160959
Guideline Name	Synagis (palivizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Synagis (palivizumab)
Prophylaxis of respiratory syncytial virus (RSV) Indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients: with a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of respiratory syncytial virus (RSV) season; with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of respiratory syncytial virus (RSV) season; with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of respiratory syncytial virus (RSV) season. Limitations of use: The safety and efficacy of Synagis have not been established for treatment of RSV disease.

2 . Criteria

Product Name: Synagis	
Diagnosis	Premature Infants (without other indications)
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - Born prematurely at or before 29 weeks, 0 days gestation [2, B]

AND

2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season [A].

AND

3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region.

AND

4 - Patient has not received Beyfortus (nirsevimab) for the current RSV season [4]

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre

	vss/rsv/index.html) to confirm the start of RSV season based on regio n.

Product Name: Synagis	
Diagnosis	Chronic Lung Disease of Prematurity
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - Chronic lung disease (CLD) of prematurity [2]

AND

2 - Born before 32 weeks, 0 days gestation [2]

AND

3 - Received greater than 21% oxygen supplementation for at least the first 28 days after birth

AND

4 - One of the following:

4.1 Age < 12 months at the start of the respiratory syncytial virus (RSV) season.

OR

4.2 Both of the following:

- Age at least 12 to < 24 months at the start of the RSV season
- Received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season

AND

5 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Neonatologist
- Pediatric intensivist
- Infectious disease specialist

AND

6 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region.

AND

7 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

Product Name: Synagis	
Diagnosis	Hemodynamically Significant Congenital Heart Disease
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - One of the following:

1.1 Age < 12 months at the start of the respiratory syncytial virus (RSV) season, with one of the following: [C] (persons of all ages).

1.1.1 All of the following:

- Acyanotic heart failure
- Receiving medication to control congestive heart failure
- Patient will require a cardiac surgical procedure

OR

1.1.2 Moderate to severe pulmonary hypertension

OR

1.1.3 Cyanotic heart defect

OR

1.2 Both of the following*: [D]

- Age < 24 months
- Patient will or has undergone a cardiac transplantation during the respiratory syncytial virus (RSV)season

AND

2 - Prescribed by or in consultation with a pediatric cardiologist

AND

3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

AND

4 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. *ONE additional postoper ative dose allowed for patients undergoing cardiac transplantation, car diac bypass or extracorporeal membrane oxygenation. [A, D] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

Product Name: Synagis	
Diagnosis	Pulmonary Abnormality or Neuromuscular Disorder
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - Pulmonary abnormalities (e.g., pulmonary malformations, tracheoesophageal fistula, conditions requiring tracheostomy) or neuromuscular disease (e.g., cerebral palsy) [2]

AND

2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season.

AND

3 - Impaired ability to clear secretions from the upper airway due to an ineffective cough

AND

4 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Neurologist

AND

5 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

AND

6 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

Product Name: Synagis

Diagnosis	Immunocompromised Children
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - Prescriber attests that patient is immunocompromised

AND

2 - Age < 24 months

AND

3 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Infectious disease specialist
- Pediatric intensivist

AND

4 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

AND

5 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis

	prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Children with Cystic Fibrosis
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
SYNAGIS	PALIVIZUMAB IM SOLN 50 MG/0.5ML	19502060002015	Brand
SYNAGIS	PALIVIZUMAB IM SOLN 100 MG/ML	19502060002020	Brand

Approval Criteria

1 - Diagnosis of cystic fibrosis [2]

AND

2 - One of the following:

2.1 Both of the following:

- Age < 12 months
- Clinical evidence of chronic lung disease (CLD) and/or nutritional compromise (i.e., failure to thrive)

OR

2.2 Both of the following:

- Age at least 12 to < 24 months

• Severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length < 10th percentile on pediatric growth chart [E] **AND** **3** - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region **AND** **4** - Patient has not received Beyfortus (nirsevimab) for the current RSV season	
Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

3 . Endnotes

A. Five monthly doses of palivizumab will provide more than 6 months of prophylactic serum palivizumab concentrations. Administration of more than five monthly doses is not recommended. If RSV season onset is in November, the first dose should be administered in November, and the fifth and final dose should be administered in March. If RSV season onset is in November and the first dose is given in January, the third and final dose should be administered in March. In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV “season” in the state of Florida that could affect the timing of palivizumab administration. [2] For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report (MMWR), season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is at least

10% and RSV season offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is at least 10%. [3] NREVSS surveillance data can be viewed here (http://www.cdc.gov/surveillance/nrevss/rsv/)

B. Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days' gestation. [2]
C. The following conditions are NOT considered hemodynamically significant congenital heart disease: secundum atrial septal defect, small ventricular septal defect, pulmonary stenosis, uncomplicated aortic stenosis, mild coaractation of the aorta, and patent ductus arteriosus; lesions adequately corrected by surgery, unless continuing required medication for congestive heart failure; mild cardiomyopathy and not receiving medical therapy for the condition; children in the second year of life. [2]
D. Pediatric growth charts can be viewed here (http://www.cdc.gov/growthcharts/who_charts.htm)
E. Children undergoing these procedures should receive an additional dose of palivizumab as soon as possible after the procedure. Thereafter, doses should be administered monthly as scheduled. [2]
F. Monthly prophylaxis should be discontinued in any infant or child who experiences a breakthrough RSV hospitalization. [2]
G. Palivizumab prophylaxis is not recommended for prevention of health care-associated RSV disease. [2]
H. The burden of RSV disease and costs associated with transport from remote locations may result in a broader use of palivizumab for RSV prevention in Alaska Native populations and possibly in selected other American Indian populations. [2]

4 . References

1. Synagis Prescribing Information. Swedish Orphan Biovitrum AB (publ). Stockholm, Sweden September 2021.
2. Commitee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalizations for respiratory syncytial virus infection. Pediatrics. 2014 Aug;134(2):415-20. doi: 10.1542/peds.2014-1665.
3. Panozzo CA, Stockman LJ, et al. Use of respiratory syncytial virus surveillance data to optimize the timing of immunoprophylaxis. Pediatrics. 2010 Jul;126(1):e116-23.
4. Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices – United States, 2023. MMWR Morb Mortal Wkly Rep. 2023;72(34):920-925

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160960
Guideline Name	Tabrecta (capmatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tabrecta (capmatinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

2 . Criteria

Product Name: Tabrecta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TABRECTA	CAPMATINIB HCL TAB 150 MG	21533716200320	Brand
TABRECTA	CAPMATINIB HCL TAB 200 MG	21533716200330	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Tabrecta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TABRECTA	CAPMATINIB HCL TAB 150 MG	21533716200320	Brand
TABRECTA	CAPMATINIB HCL TAB 200 MG	21533716200330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Tabrecta Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. March 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-158856
Guideline Name	Tadalafil
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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.

Prior Authorization Guideline

Guideline ID	GL-160961
Guideline Name	Tafinlar (dabrafenib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tafinlar (dabrafenib)
BRAF V600E mutation-positive unresectable or metastatic melanoma Indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma. **BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma** Indicated in combination with trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

BRAF V600E mutation-positive metastatic non-small cell lung cancer Indicated in combination with trametinib for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

BRAF V600E or V600K mutation-positive adjunctive treatment for melanoma Indicated for adjuvant treatment in combination with trametinib for patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

Anaplastic thyroid cancer (ATC) with BRAF V600E mutation Indicated in combination with trametinib for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

BRAF V600E mutation-positive unresectable or metastatic solid tumors Indicated, in combination with trametinib, for the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

BRAF V600E mutation-positive low-grade glioma Indicated, in combination with trametinib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Indication BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

2 . Criteria

Product Name: Tafinlar

Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - One of the following diagnoses: [2]

- Unresectable melanoma
- Metastatic melanoma

AND

2 - One of the following:

2.1 Cancer is BRAFV600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

OR

2.2 Both of the following:

2.2.1 Cancer is BRAFV600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

2.2.2 Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Tafinlar	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer

AND

2 - Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Tafinlar

Diagnosis	Adjunctive treatment for melanoma
Approval Length	12 Month [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Cancer is BRAF V600E mutation or V600K mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Involvement of lymph nodes following complete resection [2]

AND

4 - Used as adjunctive therapy

AND

5 - Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar

Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) [2]

AND

2 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Cancer may not be treated with standard locoregional treatment options

AND

4 - Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Tafinlar	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Patient is 1 year of age or older

AND

3 - Disease is one of the following:

- unresectable
- metastatic

AND

4 - Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options

AND

5 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Tafinlar	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Diagnosis of low-grade glioma

AND

2 - Patient is 1 year of age or older

AND

3 - Patient requires systemic therapy

AND

4 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAFINLAR	DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)	21532025100120	Brand
TAFINLAR	DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)	21532025100130	Brand
TAFINLAR	DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV)	21532025107320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

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. August 2023.
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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160962
Guideline Name	Tagrisso (osimertinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tagrisso (osimertinib)
First-line Treatment of EGFR Mutation-Positive Metastatic Non-Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. **Previously Treated EGFR T790M Mutation-Positive Metastatic NSCLC** Indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy. **Adjuvant Treatment of EGFR Mutation-Positive Non-Small Cell Lung Cancer (NSCLC)** Indicated as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. **First-line Treatment of EGFR Mutation-Positive Locally Advanced or Metastatic NSCLC**

Indicated in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 or exon 21 L858R mutations, as detected by an FDA-approved test.

2 . Criteria

Product Name: Tagrisso	
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 One of the following:

1.1.2.1 Both of the following:

1.1.2.1.1 Patient has a known active epidermal growth factor receptor (EGFR) T790M mutation as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.1.2.1.2 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)*

OR

1.1.2.2 Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

1.2 All of the following:

1.2.1 Diagnosis of non-small cell lung cancer (NSCLC)

AND

1.2.2 Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.2.3 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

OR

1.3 All of the following:

1.3.1 Diagnosis of NSCLC

AND

1.3.2 Disease is locally advanced

AND

1.3.3 Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.3.4 Used in combination with both of the following:

- Pemetrexed
- Platinum-based chemotherapy (e.g., cisplatin, carboplatin)

Notes	*This product may require prior authorization.

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. February 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 27, 2023.
3. National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Non-small cell lung cancer. v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 27, 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160963
Guideline Name	Tarceva (erlotinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tarceva (erlotinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. Limitations of use: Safety and efficacy of Tarceva have not been established in patients with NSCLC whose tumors have other EGFR mutations. Tarceva is not recommended for use in combination with platinum-based chemotherapy. **Pancreatic Cancer** Indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer in combination with gemcitabine.

2 . Criteria

Product Name: Brand Tarceva, Generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARCEVA	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Generic
TARCEVA	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Generic
TARCEVA	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Generic

Approval Criteria

1 - Diagnosis of locally advanced or metastatic (stage III or IV) non-small cell lung cancer (NSCLC) [2]

AND

2 - Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions, exon 21 (L858R) substitution, exon 18 (G719X, G719) or exon 20 (S7681) mutation as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

Product Name: Brand Tarceva, Generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARCEVA	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Generic
TARCEVA	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Generic
TARCEVA	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Generic

Approval Criteria

1 - One of the following diagnoses:

- Locally advanced pancreatic cancer
- Unresectable pancreatic cancer
- Metastatic pancreatic cancer

AND

2 - Used in combination with Gemzar (gemcitabine)

Product Name: Brand Tarceva, Generic erlotinib	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARCEVA	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)	21360025100320	Generic

TARCEVA	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)	21360025100330	Generic
TARCEVA	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Brand
ERLOTINIB HYDROCHLORIDE	ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)	21360025100360	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

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.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 27, 2023.
3. Erlotinib Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. January 2019.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160964
Guideline Name	Targretin (bexarotene)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Targretin (bexarotene) capsules
Cutaneous T-Cell Lymphoma Indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.
Drug Name: Targretin (bexarotene) gel 1%
Cutaneous T-Cell Lymphoma Indicated for the topical treatment of cutaneous lesions in patients with cutaneous T-cell lymphoma (Stage 1A and 1B) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

2 . Criteria

Product Name: Brand Targretin capsules, Generic bexarotene capsules, Brand Targretin gel, Generic bexarotene Gel	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARGRETIN	BEXAROTENE CAP 75 MG	21708220000120	Brand
TARGRETIN	BEXAROTENE GEL 1%	90376220004020	Brand
BEXAROTENE	BEXAROTENE CAP 75 MG	21708220000120	Generic
BEXAROTENE	BEXAROTENE GEL 1%	90376220004020	Generic

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL) [A]

AND

2 - Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids {i.e., clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}, topical mechlorethamine, phototherapy] or systemic therapies [e.g., brentuximab vedotin, methotrexate])

AND

3 - Trial and failure, contraindication, or intolerance to generic Targretin (Applies to brand Targretin only)

Product Name: Brand Targretin capsules, Generic bexarotene capsules, Brand Targretin gel, Generic bexarotene Gel	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TARGRETIN	BEXAROTENE CAP 75 MG	21708220000120	Brand
TARGRETIN	BEXAROTENE GEL 1%	90376220004020	Brand
BEXAROTENE	BEXAROTENE CAP 75 MG	21708220000120	Generic
BEXAROTENE	BEXAROTENE GEL 1%	90376220004020	Generic

Approval Criteria

1 - Patient does not show evidence of disease progression while on therapy

3 . Endnotes

A. Cutaneous T-cell lymphomas (CTCLs) are a group of non-Hodgkin's lymphomas (NHLs) primarily developing in the skin and at times progress to involve lymph nodes, blood, and visceral organs. Mycosis fungoides (MF) is the most common subtype and is usually associated with an indolent clinical course with intermittent, stable, or slow progression of the lesions. Extracutaneous involvement (lymph nodes, blood, or less commonly, other organs) or large cell transformation (LCT) may be seen in advanced-stage disease. Sezary Syndrome (SS) is a rare erythrodermic, leukemic variant of CTCL and is characterized by significant blood involvement, erythroderma, and often lymphadenopathy. Primary cutaneous CD30+ T cell lymphoproliferative disorders are also included as a subtype of CTCL. [3]

4 . References

1. Targretin prescribing information. Bausch Health US, LLC. Bridgewater, NJ. April 2020.
2. Targretin gel 1% prescribing information. Bausch Health US, LLC. Bridgewater, NJ. February 2020.
3. National Comprehensive Cancer Network (NCCN). Primary Cutaneous Lymphomas v.2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf Accessed on July 18, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160965
Guideline Name	Tasigna (nilotinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tasigna (nilotinib)
Newly diagnosed Ph+ Chronic Myeloid Leukemia Indicated for the treatment of adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. **Resistant or intolerant CML in chronic phase (CP) and accelerated phase (AP)** Indicated for the treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant to or intolerant to prior therapy that included imatinib. **Resistant or intolerant CML in chronic phase (CP) and accelerated phase (AP), Pediatric** Indicated for pediatric patients greater than or equal to 1 year of age with chronic phase and accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy.

2 . Criteria

Product Name: Tasigna	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TASIGNA	NILOTINIB HCL CAP 50 MG (BASE EQUIVALENT)	21531860200110	Brand
TASIGNA	NILOTINIB HCL CAP 150 MG (BASE EQUIVALENT)	21531860200115	Brand
TASIGNA	NILOTINIB HCL CAP 200 MG (BASE EQUIVALENT)	21531860200125	Brand

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive/BCR ABL positive (Ph+/BCR ABL) chronic myelogenous/myeloid leukemia (CML) (A)

AND

2 - Patient is 1 year of age or older

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to generic imatinib

OR

3.2 Continuation of prior therapy

Product Name: Tasigna	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TASIGNA	NILOTINIB HCL CAP 50 MG (BASE EQUIVALENT)	21531860200110	Brand
TASIGNA	NILOTINIB HCL CAP 150 MG (BASE EQUIVALENT)	21531860200115	Brand
TASIGNA	NILOTINIB HCL CAP 200 MG (BASE EQUIVALENT)	21531860200125	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to generic imatinib

OR

2.2 Continuation of prior therapy

3 . Endnotes

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.1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed March 27, 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160966
Guideline Name	Tavneos (avacopan) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-158811
Guideline Name	Tecfidera (dimethyl fumarate) - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tecfidera (dimethyl fumarate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

2 . Criteria

Product Name: Generic dimethyl fumarate	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIMETHYL FUMARATE	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 120 MG	62405525006520	Generic
DIMETHYL FUMARATE	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 240 MG	62405525006540	Generic
DIMETHYL FUMARATE STARTERPACK	DIMETHYL FUMARATE CAPSULE DR STARTER PACK 120 MG & 240 MG	6240552500B320	Generic

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [4]

AND

2 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Brand Tecfidera	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 120 MG	62405525006520	Brand
TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 240 MG	62405525006540	Brand
TECFIDERA STARTER PACK	DIMETHYL FUMARATE CAPSULE DR STARTER PACK 120 MG & 240 MG	6240552500B320	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [3]

AND

2 - All of the following:

2.1 Trial and failure of at least 4 weeks, or intolerance to generic dimethyl fumarate

AND

2.2 Trial and failure of at least 4 weeks, or intolerance to at least one of the following disease-modifying therapies for MS: [A, 5]

- Bafiertam (monomethyl fumarate)
- Vumerity (diroximel fumarate)

AND

2.3 One of the following:

2.3.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to generic fingolimod

OR

2.3.2 For continuation of therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Tecfidera, generic dimethyl fumarate	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 120 MG	62405525006520	Brand
DIMETHYL FUMARATE	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 120 MG	62405525006520	Generic
TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 240 MG	62405525006540	Brand
DIMETHYL FUMARATE	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 240 MG	62405525006540	Generic
DIMETHYL FUMARATE STARTERPACK	DIMETHYL FUMARATE CAPSULE DR STARTER PACK 120 MG & 240 MG	6240552500B320	Generic
TECFIDERA STARTER PACK	DIMETHYL FUMARATE CAPSULE DR STARTER PACK 120 MG & 240 MG	6240552500B320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - All of the following: (applies to Brand Tecfidera only)

2.1 Trial and failure of at least 4 weeks, or intolerance to generic dimethyl fumarate

AND

2.2 Trial and failure of at least 4 weeks, or intolerance to at least one of the following disease-modifying therapies for MS: [A, 5]

- Bafiertam (monomethyl fumarate)
- Vumerity (diroximel fumarate)

AND

2.3 One of the following:

2.3.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to generic fingolimod

OR

2.3.2 For continuation of therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Tecfidera	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 120 MG	62405525006520	Brand

TECFIDERA	DIMETHYL FUMARATE CAPSULE DELAYED RELEASE 240 MG	62405525006540	Brand
TECFIDERA STARTER PACK	DIMETHYL FUMARATE CAPSULE DR STARTER PACK 120 MG & 240 MG	6240552500B320	Brand

Approval Criteria

1 - 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 - Paid claims or submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to all of the following:

- Generic dimethyl fumarate
- Bafiertam (monomethyl fumarate)
- Vumerity (diroximel 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

3 . Endnotes

A. Although the trial results of Bafiertam and Vumerity were based off of Tecfidera, the consultant thinks that the two drugs should have the same efficacy and safety profile as Tecfidera since they were approved via the FDA 505(b)(2) pathway. [5]
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. March 2024.
4. Dimethyl Fumarate Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. February 2022.
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.

Prior Authorization Guideline

Guideline ID	GL-160968
Guideline Name	Tepmetko (tepotinib) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tepmetko (tepotinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

2 . Criteria

Product Name: Tepmetko	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TEPMETKO	TEPOTINIB HCL TAB 225 MG	21533773100320	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations [A]

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to Tabrecta

OR

4.2 For continuation of prior therapy

Product Name: Tepmetko	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

TEPMETKO	TEPOTINIB HCL TAB 225 MG	21533773100320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Tabrecta

OR

2.2 For continuation of prior therapy

Product Name: Tepmetko	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TEPMETKO	TEPOTINIB HCL TAB 225 MG	21533773100320	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations [A]

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Tabrecta

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . Endnotes

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.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-158814
Guideline Name	Teriparatide Products - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Forteo (teriparatide injection), Teriparatide (teriparatide injection)
Postmenopausal women with osteoporosis at high risk of fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, teriparatide reduces the risk of vertebral and nonvertebral fractures. **Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture** Indicated to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. **Men and women with glucocorticoid-induced osteoporosis at high risk for fracture** Indicated for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name: Brand Forteo, Brand Teriparatide, generic teriparatide	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture, Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FORTEO	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 600 MCG/2.4ML	3004407000D220	Brand
TERIPARATIDE	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 600 MCG/2.4ML	3004407000D220	Generic
TERIPARATIDE	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 620 MCG/2.48ML	3004407000D221	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Postmenopausal osteoporosis or osteopenia
- Primary or hypogonadal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions

- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - For Brand Forteo, trial and failure or intolerance to all of the following:

- Brand Teriparatide
- Generic teriparatide
- Tymlos (abaloparatide)

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

4.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Brand Forteo, Brand Teriparatide, generic teriparatide	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture, Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FORTEO	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 600 MCG/2.4ML	3004407000D220	Brand
TERIPARATIDE	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 600 MCG/2.4ML	3004407000D220	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, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

1.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

AND

2 - For Brand Forteo, trial and failure or intolerance to all of the following:

- Brand Teriparatide
- Generic teriparatide
- Tymlos (abaloparatide)

Product Name: Brand Forteo	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture, Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
FORTEO	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 600 MCG/2.4ML	3004407000D220	Brand

Approval Criteria

1 - Diagnosis of one of the following:

- Postmenopausal osteoporosis or osteopenia
- Primary or hypogonadal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to all of the following:

- Brand Teriparatide
- Generic teriparatide
- Tymlos (abaloparatide)

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

4.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Brand Forteo, Brand Teriparatide, generic teriparatide	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FORTEO	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 600 MCG/2.4ML	3004407000D220	Brand
TERIPARATIDE	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 600 MCG/2.4ML	3004407000D220	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 - For Brand Forteo, trial and failure or intolerance to both of the following:

- Brand Teriparatide
- Generic teriparatide

AND

6 - One of the following: [7,B]

6.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

6.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Brand Forteo, Brand Teriparatide, generic teriparatide	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
FORTEO	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 600 MCG/2.4ML	3004407000D220	Brand
TERIPARATIDE	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 600 MCG/2.4ML	3004407000D220	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, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

1.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

AND

2 - For Brand Forteo, trial and failure or intolerance to both of the following:

- Brand Teriparatide
- Generic teriparatide

Product Name: Brand Forteo	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
FORTEO	TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ 600 MCG/2.4ML	3004407000D220	Brand

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - History of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months [C]

AND

3 - One of the following: [8,A]

3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

3.4 One of the following:

- Glucocorticoid dosing of at least 30 mg per day
- Cumulative glucocorticoid dosing of at least 5 grams per year

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [E]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Brand Teriparatide
- Generic teriparatide

AND

6 - One of the following: [7,B]

6.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

6.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

3 . Definitions

Definition	Description
Dual x-ray absorptiometry (DXA) [3]	A diagnostic test used to assess bone density at various skeletal sites using radiation exposure about one-tenth that of a standard chest X-ray. Central DXA (lumbar spine, hip) is the preferred measurement for definitive diagnosis of osteoporosis and for monitoring the effects of therapy.
Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean BMD of a young adult reference population (T-score between − 1.0 and − 2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration of bone tissue, decreased bone strength, bone fragility, and a consequent increase in fracture risk; BMD 2.5 or more standard deviations below the mean BMD of a young adult reference population (T-score at or below − 2.5).
Quantitative computed tomography (QCT) [3]	A diagnostic test used to assess volumetric bone density; reflects three-dimensional BMD. Usually used to assess the lumbar spine but has been adapted for other skeletal sites (e.g., hip). It is also possible to measure trabecular and cortical bone density in the periphery by peripheral QCT (pQCT) or high-resolution pQCT (HRpQCT).
T-score [3]	In describing BMD, the number of standard deviations above or below the mean BMD of a young adult reference population.

Z-score [3]	In describing BMD, the number of standard deviations above or below the mean BMD for persons of the same age, sex, and ethnicity.

4 . Endnotes

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.
3. The Bone Health and Osteoporosis Foundation (BHOF). Clinician's guide to prevention and treatment of osteoporosis. Washington (DC): The Bone Health and Osteoporosis Foundation (BHOF); 2022

4. North American Menopause Society. Management of postmenopausal osteoporosis in postmenopausal women: 2010 position statement of the North American Menopause Society. Menopause 2010;17(1):25-54.
5. Per clinical consult with bone disease specialist, September 26, 2011.
6. Saag KG, Zanchetta JR, Devogelaer JP, et al. Effects of teriparatide versus alendronate for treating glucocorticoid-induced osteoporosis: thirty-six-month results of a randomized, double-blind, controlled trial. Arthritis Rheum. 2009;60(11):3346-55.
7. Tymlos prescribing information. Radius Health, Inc. Waltham, MA. April 2021.
8. Per clinical consultation with endocrinologists. January 23 & 30, 2018.
9. American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis: 2022 edition. Available at: https://rheumatology.org/glucocorticoid-induced-osteoporosis-guideline. Accessed May 2023.
10. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An endocrine society clinical practice guideline. J Clin Endocrin Metab. 2019; 104(5):1595-1622.
11. Teriparatide prescribing information. Alvogen, Inc. Morristown, NJ. November 2019.

Prior Authorization Guideline

Guideline ID	GL-160969
Guideline Name	Testosterone
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Androderm (testosterone [T] patch), Androgel (T gel and pump), Fortesta (T gel), Natesto (T nasal gel), Testim (T gel), and Vogelxo (T gel and pump)
Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy or toxic damage from alcohol or heavy metals. These men usually have low testosterone serum levels and gonadotropins (FSH, LH) above the normal range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males less than 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure. **Hypogonadotropic hypogonadism (congenital or acquired)** Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or

pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males less than 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Drug Name: Methitest (methyltestosterone) tablet

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Metastatic mammary cancer in females Indicated for secondary use in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchidectomy.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) is idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Drug Name: Depo-Testosterone (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Drug Name: Testopel (testosterone) pellet

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism" have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired)- idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism" have not been established.

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Drug Name: Aveed (testosterone undecanoate) injection

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired): testicular failure due to

cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Drug Name: Testone CIK (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy. Limitations of Use: Safety and efficacy of testosterone cypionate in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of Use: Safety and efficacy of testosterone cypionate in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Drug Name: Xyosted (testosterone enanthate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter’s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement

therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Drug Name: Jatenzo (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established.

Drug Name: Tlando (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Drug Name: Kyzatrex (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to

cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Drug Name: Androderm, Androgel, Aveed, 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.

2 . Criteria

Product Name: Androderm, Brand Androgel gel and pump (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Natesto, Generic testosterone gel 25 mg/2.5 g (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone gel pump (1%), Generic testosterone topical solution 30 mg/act, Generic testosterone gel 10 mg/act (2%), Aveed, Generic testosterone enanthate, Brand

Depo-Testosterone, Brand Fortesta, Brand Testim, Brand Testosterone Cypionate, Testone CIK, Testopel, Testosterone implant pellets, Xyosted, Brand Vogelxo	
Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ANDRODERM	TESTOSTERONE TD PATCH 24HR 2 MG/24HR	23100030008503	Brand
ANDRODERM	TESTOSTERONE TD PATCH 24HR 4 MG/24HR	23100030008510	Brand
FORTESTA	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Brand
ANDROGEL	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
TESTIM	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
ANDROGEL	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 1.25 GM/ACT (1%)	23100030004040	Brand
ANDROGEL	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Brand
ANDROGEL	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Brand
VOGELXO	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
VOGELXO PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Generic
NATESTO	TESTOSTERONE NASAL GEL 5.5 MG/ACT	23100030004080	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Generic
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Brand
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Brand
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML	23100030202010	Generic
TESTOPEL	TESTOSTERONE IMPLANT PELLETS 75 MG	23100030008920	Brand

AVEED	TESTOSTERONE UNDECANOATE IM INJ IN OIL 750 MG/3ML (250MG/ML)	23100030802030	Brand
TESTONE CIK	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML KIT	23100030106415	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 50 MG/0.5ML	2310003020D520	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 75 MG/0.5ML	2310003020D530	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 100 MG/0.5ML	2310003020D540	Brand
TESTOSTERONE	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE TOPICAL SOLUTION	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 50 MG/ML	23100030102055	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 100 MG/ML	23100030102060	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 150 MG/ML	23100030102065	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML	23100030102070	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 25 MG	23100030008910	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 50 MG	23100030008915	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 100 MG	23100030008930	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 200 MG	23100030008940	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 37.5 MG	23100030008912	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 87.5 MG	23100030008925	Brand

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab** [7, 9]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to both of the following (applies to Aveed, Testopel, Testosterone implant pellets, Testone CIK, Brand Depo-Testosterone, Brand Testosterone Cypionate only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

6 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

7 - Trial and failure or intolerance to generic testosterone gel (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, and Brand Natesto only)

Notes	**This may require treatment to be temporarily held.

Product Name: Generic testosterone cypionate	
Diagnosis	Male hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Generic

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab** [7, 8]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

Notes	**This may require treatment to be temporarily held.

Product Name: Methitest, Generic methyltestosterone, Jatenzo, Kyzatrex, Tlando	
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

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab*** [7, 8]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab***

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to both of the following:

- Androderm (testosterone patch)
- Generic testosterone gel

Notes	***This may require treatment to be temporarily held.

Product Name: Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Brand Fortesta, Generic testosterone gel 10 mg/act (2)%, Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Testosterone Cypionate, Testone CIK, Testopel, Testosterone implant pellets, Tlando, Xyosted	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26 D]
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ANDRODERM	TESTOSTERONE TD PATCH 24HR 2 MG/24HR	23100030008503	Brand
ANDRODERM	TESTOSTERONE TD PATCH 24HR 4 MG/24HR	23100030008510	Brand
FORTESTA	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Brand
ANDROGEL	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
TESTIM	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	Brand
ANDROGEL	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 1.25 GM/ACT (1%)	23100030004040	Brand
ANDROGEL	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Brand
ANDROGEL	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Brand
VOGELXO	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
VOGELXO PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Generic
NATESTO	TESTOSTERONE NASAL GEL 5.5 MG/ACT	23100030004080	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Generic
METHYLTESTOSTERONE	METHYLTESTOSTERONE CAP 10 MG	23100020000105	Generic
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Brand
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Brand

TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML	23100030202010	Generic
TESTOPEL	TESTOSTERONE IMPLANT PELLETS 75 MG	23100030008920	Brand
AVEED	TESTOSTERONE UNDECANOATE IM INJ IN OIL 750 MG/3ML (250MG/ML)	23100030802030	Brand
TESTONE CIK	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML KIT	23100030106415	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 50 MG/0.5ML	2310003020D520	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 75 MG/0.5ML	2310003020D530	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 100 MG/0.5ML	2310003020D540	Brand
TESTOSTERONE	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE TOPICAL SOLUTION	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 50 MG/ML	23100030102055	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 100 MG/ML	23100030102060	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 150 MG/ML	23100030102065	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML	23100030102070	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 25 MG	23100030008910	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 50 MG	23100030008915	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 100 MG	23100030008930	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 200 MG	23100030008940	Brand

KYZATREX	TESTOSTERONE UNDECANOATE CAP 100 MG	23100030800124	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 150 MG	23100030800128	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 158 MG	23100030800130	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 198 MG	23100030800135	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 237 MG	23100030800140	Brand
TLANDO	TESTOSTERONE UNDECANOATE CAP 112.5 MG	23100030800125	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 37.5 MG	23100030008912	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 87.5 MG	23100030008925	Brand

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

AND

3 - Trial and failure or intolerance to both of the following (applies to Aveed, Testopel, Testosterone implant pellets, Testone CIK, Brand Depo-Testosterone, Brand Testosterone Cypionate):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

4 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

5 - Trial and failure or intolerance to generic testosterone (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, Brand Natesto only)

Product Name: Generic testosterone cypionate	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26 D]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Generic

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

Product Name: Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Brand Fortesta, Generic testosterone gel 10 mg/act (2)%, Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Testosterone Cypionate, Generic testosterone cypionate, Testone CIK, Testopel, Testosterone implant pellets, Tlando, Xyosted

Diagnosis	Male hypogonadism, Gender dysphoria/Gender incongruence
Approval Length	12 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ANDRODERM	TESTOSTERONE TD PATCH 24HR 2 MG/24HR	23100030008503	Brand
ANDRODERM	TESTOSTERONE TD PATCH 24HR 4 MG/24HR	23100030008510	Brand
FORTESTA	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Brand
ANDROGEL	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
TESTIM	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	Brand
ANDROGEL	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 1.25 GM/ACT (1%)	23100030004040	Brand
ANDROGEL	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Brand
ANDROGEL	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Brand
ANDROGEL PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Brand
VOGELXO	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Brand
VOGELXO PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 50 MG/5GM (1%)	23100030004030	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 12.5 MG/ACT (1%)	23100030004040	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 10MG/ACT (2%)	23100030004070	Generic
NATESTO	TESTOSTERONE NASAL GEL 5.5 MG/ACT	23100030004080	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 25 MG/2.5GM (1%)	23100030004025	Generic
METHYLTESTOSTERONE	METHYLTESTOSTERONE CAP 10 MG	23100020000105	Generic

DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Generic
DEPO-TESTOSTERONE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Generic
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML	23100030202010	Generic
TESTOPEL	TESTOSTERONE IMPLANT PELLETS 75 MG	23100030008920	Brand
AVEED	TESTOSTERONE UNDECANOATE IM INJ IN OIL 750 MG/3ML (250MG/ML)	23100030802030	Brand
TESTONE CIK	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML KIT	23100030106415	Brand
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)	23100030004044	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)	23100030004047	Generic
TESTOSTERONE	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
TESTOSTERONE PUMP	TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)	23100030004050	Generic
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 50 MG/0.5ML	2310003020D520	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 75 MG/0.5ML	2310003020D530	Brand
XYOSTED	TESTOSTERONE ENANTHATE SOLUTION AUTO-INJECTOR 100 MG/0.5ML	2310003020D540	Brand
TESTOSTERONE	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE TOPICAL SOLUTION	TESTOSTERONE TD SOLN 30 MG/ACT	23100030002020	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 50 MG/ML	23100030102055	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 100 MG/ML	23100030102060	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 150 MG/ML	23100030102065	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML	23100030102070	Brand

TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 25 MG	23100030008910	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 50 MG	23100030008915	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 100 MG	23100030008930	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 200 MG	23100030008940	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 158 MG	23100030800130	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 198 MG	23100030800135	Brand
JATENZO	TESTOSTERONE UNDECANOATE CAP 237 MG	23100030800140	Brand
TLANDO	TESTOSTERONE UNDECANOATE CAP 112.5 MG	23100030800125	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 100 MG	23100030800124	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 150 MG	23100030800128	Brand
KYZATREX	TESTOSTERONE UNDECANOATE CAP 200 MG	23100030800136	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 37.5 MG	23100030008912	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 87.5 MG	23100030008925	Brand

Approval Criteria

1 - One of the following:

1.1 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.2 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

OR

1.3 Both of the following:

1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.3.2 One of the following:

1.3.2.1 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.3.2.2 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

2 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

- Generic testosterone cypionate
- Generic testosterone enanthate

Product Name: Methitest, Generic testosterone enanthate, Testopel, Testosterone implant pellets, Generic methyltestosterone, Brand Testosterone Cypionate [off-label]			
Diagnosis	Delayed puberty [E]		
Approval Length	6 month(s)		
Guideline Type	Prior Authorization		
Product Name	Generic Name	GPI	Brand/Generic

METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	Brand
METHYLTESTOSTERONE	METHYLTESTOSTERONE CAP 10 MG	23100020000105	Generic
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML	23100030202010	Generic
TESTOPEL	TESTOSTERONE IMPLANT PELLETS 75 MG	23100030008920	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 50 MG/ML	23100030102055	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 100 MG/ML	23100030102060	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 150 MG/ML	23100030102065	Brand
TESTOSTERONE CYPIONATE	TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML	23100030102070	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 25 MG	23100030008910	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 50 MG	23100030008915	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 100 MG	23100030008930	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 200 MG	23100030008940	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 37.5 MG	23100030008912	Brand
TESTOSTERONE	TESTOSTERONE IMPLANT PELLETS 87.5 MG	23100030008925	Brand

Approval Criteria

1 - Diagnosis of delayed puberty [A]

AND

2 - Male patient at birth [C]

AND

3 - Trial and failure or intolerance to both of the following (applies to Testopel and Testosterone implant pellets only):

- Generic testosterone cypionate [F]
- Generic testosterone enanthate

Product Name: Generic testosterone cypionate [off-label]	
Diagnosis	Delayed puberty [E]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML	23100030102010	Generic
TESTOSTERONE CYPIONATE	TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML	23100030102015	Generic

Approval Criteria

1 - Diagnosis of delayed puberty [A]

AND

2 - Male patient at birth [C]

Product Name: Methitest, Generic methyltestosterone, Generic testosterone enanthate	
Diagnosis	Inoperable breast cancer in women
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
METHITEST	METHYLTESTOSTERONE ORAL TAB 10 MG	23100020000310	Brand
METHYLTESTOSTERONE	METHYLTESTOSTERONE CAP 10 MG	23100020000105	Generic

TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML	23100030202010	Generic

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Breast cancer is inoperable

AND

3 - Used for palliative treatment

AND

4 - Female patient at birth [C]

3 . Endnotes

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

1. Androderm Prescribing Information. Allergan Inc. Madison, NJ. May 2020.
2. Androgel Prescribing Information. Abbvie, Inc. North Chicago, IL. May 2019.
3. Androgel 1.62% Prescribing Information. AbbVie Inc. North Chicago, IL. February 2019.
4. Fortesta Prescribing Information. Endo Pharmaceuticals. Malvern, PA. June 2020.
5. Methitest Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. October 2018.
6. Testim Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. August 2021.
7. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency: AUA guideline. J Urol 2018; S0022-5347(18)42817-0.
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9. Palmert MR, Dunkel L. Clinical practice. Delayed puberty. N Engl J Med. 2012; 2;366(5):443-53.
10. Vogelxo Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. April 2020.
11. Hembree, Wylie C, et al. "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline." J Clin Endocrinol Metab. November 2017, 102(11):3869-3903.
12. DRUGDEX ® [Internet database]. Greenwood Village, Colo: Thomson MICROMEDEX, updated periodically. Accessed February 7, 2022.
13. Natesto Prescribing Information. Trimel BioPharma SRL. Eaglewood, CO. September 2017.
14. Testosterone Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. July 2017.
15. Testosterone Pump Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. July 2017.

16. Methyltestosterone Prescribing Information. Impax Generics. Hayward, CA. January 2017.
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18. Depo-Testosterone Prescribing information. Pfizer. New York, NY. November 2018.
19. Testosterone Enanthate Prescribing Information. Actavis Pharma, Inc. Corona, CA. December 2017.
20. Testopel Prescribing Information. Slate Pharma. Rye, NY. August 2018.
21. Aveed Prescribing Information. Endo Pharmaceuticals Solutions Inc. August 2021.
22. Testone CIK Prescribing Information. Asclemed USA, Inc. Torrance, CA. November 2018.
23. Xyosted Prescribing Information. Antares Pharma, Inc. Ewing, NJ. November 2019.
24. Jatenzo Prescribing Information. Clarus Therapeutics, Inc. Northbrook, IL. June 2019.
25. Per clinical consultation with endocrinology specialist, March 02, 2020.
26. World Health Organization. ICD-11: International classification of diseases (11th revision).
27. Tlando Prescribing Information. Antares Pharma, Inc. Ewing, NJ. March 2022.
28. Deutsch, MB, Amato P, Coureu M, et al. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People; 2nd edition. UCSF Gender Affirming Health Program, Department of Family and Community Medicine, University of California San Francisco. June 2016
29. Health Care for Transgender and Gender Diverse Individuals: ACOG Committee Opinion, Number 823. American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice.137(3):e75-e88, 2021
30. Kyzatrex Prescribing Information. Marius Pharmaceuticals. Raleigh, NC. July 2022.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160970
Guideline Name	Thalomid (thalidomide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Thalomid (thalidomide)
Erythema Nodosum Leprosum (ENL) Indicated for the acute treatment of the cutaneous manifestations of moderate to severe ENL. Not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. Also indicated as a maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. **Newly Diagnosed Multiple Myeloma** Indicated in combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma.

2 . Criteria

Product Name: Thalomid

Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
THALOMID	THALIDOMIDE CAP 50 MG	99392070000120	Brand
THALOMID	THALIDOMIDE CAP 100 MG	99392070000130	Brand
THALOMID	THALIDOMIDE CAP 150 MG	99392070000135	Brand
THALOMID	THALIDOMIDE CAP 200 MG	99392070000140	Brand

Approval Criteria

1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL) with cutaneous manifestations

AND

2 - Thalomid is not used as monotherapy if moderate to severe neuritis is present

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
THALOMID	THALIDOMIDE CAP 50 MG	99392070000120	Brand
THALOMID	THALIDOMIDE CAP 100 MG	99392070000130	Brand
THALOMID	THALIDOMIDE CAP 150 MG	99392070000135	Brand
THALOMID	THALIDOMIDE CAP 200 MG	99392070000140	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
THALOMID	THALIDOMIDE CAP 50 MG	99392070000120	Brand
THALOMID	THALIDOMIDE CAP 100 MG	99392070000130	Brand
THALOMID	THALIDOMIDE CAP 150 MG	99392070000135	Brand
THALOMID	THALIDOMIDE CAP 200 MG	99392070000140	Brand

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Used in combination with dexamethasone, unless the patient has an intolerance to steroids

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
THALOMID	THALIDOMIDE CAP 50 MG	99392070000120	Brand
THALOMID	THALIDOMIDE CAP 100 MG	99392070000130	Brand
THALOMID	THALIDOMIDE CAP 150 MG	99392070000135	Brand
THALOMID	THALIDOMIDE CAP 200 MG	99392070000140	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Thalomid Prescribing Information. Celgene Corporation. Summit, NJ. December 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160971
Guideline Name	Tobramycin Inhaled Products - ST, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Bethkis (tobramycin) Inhalation Solution
Cystic Fibrosis Indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of six years, patients with FEV 1 less than 40% or greater than 80% predicted, or patients colonized with Burkholderia cepacia.
Drug Name: Kitabis Pak (co-packaged tobramycin inhalation solution PARI LC PLUS reusable nebulizer)
Cystic fibrosis Indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with P. aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 less than 25% or greater than 75% predicted, or patients colonized with Burkholderia cepacia.
Drug Name: TOBI (tobramycin) Inhalation Solution

Cystic fibrosis Indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with Pseudomonas aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with forced expiratory volume in 1 second (FEV1) <25% or >75% predicted, or patients colonized with Burkholderia cepacia.

2 . Criteria

Product Name: Brand Bethkis Inhalation Solution, Kitabis Pak, Brand TOBI Inhalation Solution	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
TOBI	TOBRAMYCIN NEBU SOLN 300 MG/5ML	07000070002520	Brand
KITABIS PAK	TOBRAMYCIN NEBU SOLN 300 MG/5ML	07000070002520	Brand
BETHKIS	TOBRAMYCIN NEBU SOLN 300 MG/4ML	07000070002530	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication.

AND

2 - Trial and failure of a minimum 30 day supply, or intolerance to both of the following:

- generic tobramycin 300 mg/4 ml nebulized solution
- generic tobramycin 300 mg/5 ml nebulized solution

Product Name: Brand Bethkis Inhalation Solution, Kitabis Pak, Brand TOBI Inhalation Solution	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
TOBI	TOBRAMYCIN NEBU SOLN 300 MG/5ML	07000070002520	Brand
KITABIS PAK	TOBRAMYCIN NEBU SOLN 300 MG/5ML	07000070002520	Brand
BETHKIS	TOBRAMYCIN NEBU SOLN 300 MG/4ML	07000070002530	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication.

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure of a minimum 30 day supply, or intolerance to both of the following:

- generic tobramycin 300 mg/4 ml nebulized solution
- generic tobramycin 300 mg/5 ml nebulized solution

3 . References

1. Kitabis Pak Prescribing Information. Catalent Pharma Solutions, LLC. Woodstock, IL. April 2023.
2. TOBI Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. February 2023.
3. Bethkis Prescribing Information. Chiesi USA, Inc. Woodstock, IL. February 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-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
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)

- Minimum duration of a 2-week trial of systemic glucocorticoid (e.g., prednisone)

AND

4 - Both of the following: (Applies to Tofidence IV, Tyenne IV or SC only)

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

4.2 Submission of medical records documenting why the covered product has not been effective

Product Name: Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand

TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

Product Name: Actemra IV or SC, Tofidence IV [off-label], Tyenne IV or SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand

TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Diagnosis of giant cell arteritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to a glucocorticoid

AND

4 - Both of the following: (Applies to Tofidence IV, Tyenne IV or SC only)

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

4.2 Submission of medical records documenting why the covered product has not been effective

Product Name: Actemra IV or SC, Tofidence IV [off-label], Tyenne IV or SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

Product Name: Actemra SC, Tyenne SC [off-label]	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand

TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following [6-8]:

1.1 Exclusion of other known causes of interstitial lung disease (ILD)

AND

1.2 One of the following:

1.2.1 In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD

AND

2 - Prescribed by or in consultation with a pulmonologist or rheumatologist

AND

3 - Both of the following: (Applies to Tyenne SC only)

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

3.2 Submission of medical records documenting why the covered product has not been effective

Product Name: Actemra SC, Tyenne SC [off-label]	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML	6650007000E520	Brand
ACTEMRA ACTPEN	TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 162 MG/0.9ML	6650007000D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN AUTO-INJ 162 MG/0.9ML	6650007017D520	Brand
TYENNE	TOCILIZUMAB-AAZG SUBCUTANEOUS SOLN PREF SYR 162 MG/0.9ML	6650007017E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

Product Name: Actemra IV, Tofidence IV [off-label], Tyenne IV [off-label]	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Days [B]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand

TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand

Approval Criteria

1 - Diagnosis of COVID-19

AND

2 - Patient is hospitalized

AND

3 - Currently receiving systemic corticosteroids

AND

4 - Patient requires one of the following:

- Supplemental oxygen
- Non-invasive mechanical ventilation
- Invasive mechanical ventilation
- Extracorporeal membrane oxygenation (ECMO)

AND

5 - Both of the following: (Applies to Tofidence IV and Tyenne IV only)

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of Actemra (tocilizumab)

AND

5.2 Submission of medical records documenting why the covered product has not been effective

Product Name: Actemra IV, Tofidence IV [off-label], Tyenne IV [off-label]	
Diagnosis	Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy
Approval Length	2 Months [A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ACTEMRA	TOCILIZUMAB IV INJ 80 MG/4ML	66500070002030	Brand
ACTEMRA	TOCILIZUMAB IV INJ 200 MG/10ML	66500070002035	Brand
ACTEMRA	TOCILIZUMAB IV INJ 400 MG/20ML	66500070002040	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 80 MG/4ML	66500070152030	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 200 MG/10ML	66500070152035	Brand
TOFIDENCE	TOCILIZUMAB-BAVI IV INJ 400 MG/20ML	66500070152040	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 80 MG/4ML	66500070172030	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 200 MG/10ML	66500070172035	Brand
TYENNE	TOCILIZUMAB-AAZG IV INJ 400 MG/20ML	66500070172040	Brand

Approval Criteria

1 - Patient will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy (e.g., Kymriah [tisagenlecleucel], Yescarta [axicabtagene ciloleucel])

AND

2 - Prescribed by or in consultation with an oncologist or hematologist

AND

3 - Both of the following: (Applies to Tofidence IV and Tyenne IV only)

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of Actemra (tocilizumab) **AND** **3.2** Submission of medical records documenting why the covered product has not been effective

3 . Background

Benefit/Coverage/Program Information
Formulary Adalimumab Products Adalimumab-adaz Hyrimoz Hadlima Adalimumab-fkjp

4 . Endnotes

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-160972
Guideline Name	Tolvaptan Products - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Samsca (tolvaptan)
Hyponatremia, hypervolemic and euvolemic Indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH). Important limitations: Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Samsca. It has not been established that raising serum sodium with Samsca provides a symptomatic benefit to patients.
Drug Name: Jynarque (tolvaptan)
Autosomal Dominant Polycystic Kidney Disease Indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

2 . Criteria

Product Name: Brand Samsca or Generic tolvaptan	
Approval Length	30 Days [1]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TOLVAPTAN	TOLVAPTAN TAB 15 MG	30454060000320	Generic
SAMSCA	TOLVAPTAN TAB 15 MG	30454060000320	Brand
TOLVAPTAN	TOLVAPTAN TAB 30 MG	30454060000330	Generic
SAMSCA	TOLVAPTAN TAB 30 MG	30454060000330	Brand

Approval Criteria

1 - One of the following:

- Diagnosis of significant euvolemic hyponatremia [1-3, A-B]
- Diagnosis of significant hypervolemic hyponatremia [1-3, A, C]

AND

2 - Treatment has been initiated or re-initiated in a hospital setting prior to discharge within the past 30 days [1, D]

AND

3 - Trial and failure or intolerance to generic tolvaptan (applies to Brand Samsca only)

Product Name: Jynarque	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JYNARQUE	TOLVAPTAN TAB 15 MG	30454060000320	Brand
JYNARQUE	TOLVAPTAN TAB 30 MG	30454060000330	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 15 MG	3045406000B710	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 30 & 15 MG	3045406000B720	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 45 & 15 MG	3045406000B725	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 60 & 30 MG	3045406000B735	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 90 & 30 MG	3045406000B745	Brand

Approval Criteria

1 - Diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is new to therapy or has received Jynarque for less than or equal to 18 months

AND

2.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

2.2 Both of the following:

2.2.1 Patient has received Jynarque for longer than 18 months

AND

2.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

AND

3 - Patient does not have a history of significant liver impairment or injury, not including uncomplicated polycystic liver disease [E]

Product Name: Jynarque	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JYNARQUE	TOLVAPTAN TAB 15 MG	30454060000320	Brand
JYNARQUE	TOLVAPTAN TAB 30 MG	30454060000330	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 15 MG	3045406000B710	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 30 & 15 MG	3045406000B720	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 45 & 15 MG	3045406000B725	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 60 & 30 MG	3045406000B735	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 90 & 30 MG	3045406000B745	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient does not have signs or symptoms consistent with hepatic injury [E]

OR

2.2 Patient has uncomplicated polycystic liver disease

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

3.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

3.2 Both of the following:

3.2.1 Patient has received Jynarque for longer than 18 months

AND

3.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

Product Name: Jynarque	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic

JYNARQUE	TOLVAPTAN TAB 15 MG	30454060000320	Brand
JYNARQUE	TOLVAPTAN TAB 30 MG	30454060000330	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 15 MG	3045406000B710	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 30 & 15 MG	3045406000B720	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 45 & 15 MG	3045406000B725	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 60 & 30 MG	3045406000B735	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 90 & 30 MG	3045406000B745	Brand

Approval Criteria

1 - Diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Both of the following:

2.1.1 Patient is new to therapy or has received Jynarque for less than or equal to 18 months

AND

2.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

2.2 Both of the following:

2.2.1 Patient has received Jynarque for longer than 18 months

AND

2.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

AND

3 - Patient does not have a history of significant liver impairment or injury, not including uncomplicated polycystic liver disease [E]

Product Name: Jynarque	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
JYNARQUE	TOLVAPTAN TAB 15 MG	30454060000320	Brand
JYNARQUE	TOLVAPTAN TAB 30 MG	30454060000330	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 15 MG	3045406000B710	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 30 & 15 MG	3045406000B720	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 45 & 15 MG	3045406000B725	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 60 & 30 MG	3045406000B735	Brand
JYNARQUE	TOLVAPTAN TAB THERAPY PACK 90 & 30 MG	3045406000B745	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient does not have signs or symptoms consistent with hepatic injury [E]

OR

2.2 Patient has uncomplicated polycystic liver disease

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Both of the following:

3.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

3.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

3.2 Both of the following:

3.2.1 Patient has received Jynarque for longer than 18 months

AND

3.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

3 . Endnotes

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160973
Guideline Name	Topical Antifungals - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ciclopirox Kit (ciclopirox)
Onychomycosis Indicated as topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement, due to Trichophyton rubrum. The comprehensive management program includes removal of the unattached, infected nails as frequently as monthly, by a health care professional who has special competence in the diagnosis and treatment of nail disorders, including minor nail procedures.
Drug Name: Jublia (efinaconazole) topical solution
Onychomycosis of the toenails Indicated for the topical treatment of onychomycosis of the toenail(s) due to Trichophyton rubrum and Trichophyton mentagrophytes.
Drug Name: Kerydin (tavaborole) topical solution

Onychomycosis of the toenails Indicated for the treatment of onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes.

2 . Criteria

Product Name: Ciclopirox Kit	
Diagnosis	Fingernail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
CICLOPIROX TREATMENT	CICLOPIROX SOLUTION KIT 8%	90150030006420	Generic

Approval Criteria

1 - Diagnosis of onychomycosis of the fingernail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of fingernail onychomycosis has been confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Culture
- Histology

AND

4 - Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine [B]

Product Name: Ciclopirox Kit, Generic tavaborole, Jublia	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
JUBLIA	EFINACONAZOLE SOLN 10%	90154037002020	Brand
CICLOPIROX TREATMENT	CICLOPIROX SOLUTION KIT 8%	90150030006420	Generic
TAVABOROLE	TAVABOROLE SOLN 5%	90156080002010	Generic

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Culture
- Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Trial and failure, contraindication (of a minimum 12-week supply), or intolerance to oral terbinafine [B]

Product Name: Brand Kerydin	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
KERYDIN	TAVABOROLE SOLN 5%	90156080002010	Brand

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Culture
- Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Both of the following:

5.1 Trial and failure, contraindication (of a minimum 12-week supply), or intolerance to oral terbinafine [B]

AND

5.2 Trial and failure (of a minimum 48-week supply), contraindication, or intolerance to generic tavaborole

Product Name: Jublia	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
JUBLIA	EFINACONAZOLE SOLN 10%	90154037002020	Brand

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation

- Culture
- Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Treatment is requested due to a documented medical condition and not for cosmetic purposes (e.g. patients with history of cellulitis of the lower extremity, patients with diabetes who have additional risk factors for cellulitis of lower extremity, patients who experience pain/discomfort associated with the infected nail)

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to 12 weeks of treatment with ciclopirox

OR

6.2 Patient is 6 to 12 years of age

AND

7 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to 12 weeks of treatment with ONE of the following oral antifungal agents:

- itraconazole
- terbinafine
- griseofulvin

3 . Endnotes

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160974
Guideline Name	Topical Immunomodulators
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Elidel (pimecrolimus)
Mild to Moderate Atopic Dermatitis Indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.
Drug Name: Protopic (tacrolimus)
Moderate to Severe Atopic Dermatitis Indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

2 . Criteria

Product Name: Brand Elidel cream, generic pimecrolimus cream, Brand Protopic ointment	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Product Name	Generic Name	GPI	Brand/Generic
ELIDEL	PIMECROLIMUS CREAM 1%	90784060003720	Brand
PIMECROLIMUS	PIMECROLIMUS CREAM 1%	90784060003720	Generic
PROTOPIC	TACROLIMUS OINT 0.03%	90784075004210	Brand
PROTOPIC	TACROLIMUS OINT 0.1%	90784075004230	Brand

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance of generic tacrolimus ointment

3 . References

1. Elidel Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2020.
2. Protopic Prescribing Information. LEO Pharma Inc. Madison, NJ. June 2022.
3. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023 Jul;89(1):e1-e20. doi: 10.1016/j.jaad.2022.12.029. Epub 2023 Jan 12. PMID: 36641009.

4 . Revision History

Date	Notes

11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-158821
Guideline Name	Topical Retinoid Agents
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Atralin (tretinoin), Avita (tretinoin) cream and gel, Retin-A (tretinoin) cream and gel, Retin-A Micro (tretinoin) gel
Acne vulgaris Indicated for the topical treatment of acne vulgaris. **Off Label Uses: Wound healing (mild) [9]** Tretinoin 0.05% cream has been shown to decrease would healing time in patients receiving electroepilation. Enhanced healing of epidermal wounds in patients undergoing dermabrasion when pretreated with tretinoin 0.05% cream has been reported. DRUGDEX Recommendation: Adult, Class IIb, Evidence favors efficacy. **Actinic keratosis [9]** **Hyperkeratosis [9]** **Keloid scar [9]**
Drug Name: Aklief (trifarotene) cream, Arazlo (tazarotene) lotion

Acne vulgaris Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Drug Name: Altreno (tretinoin) lotion

Acne vulgaris Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Off Label Uses: Wound healing (mild) [9] Tretinoin 0.05% cream has been shown to decrease would healing time in patients receiving electroepilation. Enhanced healing of epidermal wounds in patients undergoing dermabrasion when pretreated with tretinoin 0.05% cream has been reported. DRUGDEX Recommendation: Adult, Class IIb, Evidence favors efficacy.

Actinic keratosis [9]

Hyperkeratosis [9]

Keloid scar [9]

Drug Name: Differin (adapalene) cream/lotion/gel/solution/pads

Acne vulgaris Indicated for the topical treatment of acne vulgaris.

Drug Name: Tazorac (tazarotene) cream 0.1%

Acne Vulgaris Indicated for the topical treatment of patients with acne vulgaris.

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis.

Drug Name: Tazorac (tazarotene) cream 0.05%

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis.

Drug Name: Tazorac (tazarotene) gel 0.1%

Acne Vulgaris Indicated for the topical treatment of patients with facial acne vulgaris of mild to moderate severity.

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement.

Drug Name: Tazorac (tazarotene) gel 0.05%

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement.

Drug Name: Fabior (tazarotene) foam

Acne Vulgaris Indicated for the topical treatment of acne vulgaris in patients 12 years of age or older.

2 . Criteria

Product Name: Avita, Brand Retin A Micro (0.06%, 0.08%)	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.08%	90050030204020	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.06%	90050030204017	Brand
AVITA	TRETINOIN CREAM 0.025%	90050030003703	Generic
AVITA	TRETINOIN GEL 0.025%	90050030004010	Generic

Approval Criteria

1 - One of the following:

1.1 Patient is 25 years of age or younger

OR

1.2 Both of the following:

- Patient is older than 25 years of age
- Diagnosis of acne vulgaris (i.e., acne)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Avita, Brand Retin A Micro (0.06%, 0.08%)	
Diagnosis	Other Medical Uses (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.08%	90050030204020	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.06%	90050030204017	Brand
AVITA	TRETINOIN CREAM 0.025%	90050030003703	Generic
AVITA	TRETINOIN GEL 0.025%	90050030004010	Generic

Approval Criteria

1 - One of the following diagnoses: [A, 9]

- Actinic keratosis
- Hyperkeratosis
- Keloid scar
- Wound healing (mild)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Aklief	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
AKLIEF	TRIFAROTENE CREAM 0.005%	90050035003720	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one of the following generics:

- Adapalene (cream, gel)
- Topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one of the following generics:

- Adapalene (cream, gel)
- Topical tretinoin or tretinoin microsphere

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Altreno, Atralin, Brand Retin-A, Brand Retin-A Micro (0.1% 0.04%), Brand Adapalene 0.1% Soln, Brand Adapalene 0.1% Pads	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETIN-A	TRETINOIN CREAM 0.025%	90050030003703	Brand
RETIN-A	TRETINOIN CREAM 0.05%	90050030003705	Brand
RETIN-A	TRETINOIN CREAM 0.1%	90050030003710	Brand
RETIN-A	TRETINOIN GEL 0.01%	90050030004005	Brand
RETIN-A	TRETINOIN GEL 0.025%	90050030004010	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.04%	90050030204015	Brand
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.04%	90050030204015	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.1%	90050030204030	Brand
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.1%	90050030204030	Brand
ATRALIN	TRETINOIN GEL 0.05%	90050030004015	Brand
ALTRENO	TRETINOIN LOTION 0.05%	90050030004130	Brand
ADAPALENE	ADAPALENE SOLN 0.1%	90050003002010	Brand
ADAPALENE	ADAPALENE PADS 0.1%	90050003004310	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

- Adapalene (cream, gel)
- Topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

- Adapalene (cream, gel)
- Topical tretinoin or tretinoin microsphere

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Altreno, Atralin, Brand Retin-A, Brand Retin-A Micro (0.04%, 0.1%)	
Diagnosis	Other Medical Uses (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
RETIN-A	TRETINOIN CREAM 0.025%	90050030003703	Brand
RETIN-A	TRETINOIN CREAM 0.05%	90050030003705	Brand
RETIN-A	TRETINOIN CREAM 0.1%	90050030003710	Brand
RETIN-A	TRETINOIN GEL 0.01%	90050030004005	Brand
RETIN-A	TRETINOIN GEL 0.025%	90050030004010	Brand
ALTRENO	TRETINOIN LOTION 0.05%	90050030004130	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.04%	90050030204015	Brand
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.04%	90050030204015	Brand
RETIN-A MICRO	TRETINOIN MICROSPHERE GEL 0.1%	90050030204030	Brand
RETIN-A MICRO PUMP	TRETINOIN MICROSPHERE GEL 0.1%	90050030204030	Brand
ATRALIN	TRETINOIN GEL 0.05%	90050030004015	Brand

Approval Criteria

1 - One of the following diagnoses: [A, 9]

- Actinic keratosis
- Hyperkeratosis
- Keloid Scar
- Wound healing (mild)

AND

2 - Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to any generic topical tretinoin product

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Brand Differin

Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
DIFFERIN	ADAPALENE CREAM 0.1%	90050003003710	Brand
DIFFERIN	ADAPALENE GEL 0.1%	90050003004010	Brand
DIFFERIN	ADAPALENE GEL 0.3%	90050003004030	Brand
DIFFERIN	ADAPALENE LOTION 0.1%	90050003004110	Generic

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

- adapalene (cream, gel)
- Topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

- adapalene (cream, gel)
- Topical tretinoin or tretinoin microsphere

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Arazlo, Fabior, Brand Tazarotene 0.1% foam, Brand Tazorac 0.1% cream and gel	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZORAC	TAZAROTENE CREAM 0.1%	90250070003730	Brand
TAZORAC	TAZAROTENE GEL 0.1%	90250070004030	Brand
FABIOR	TAZAROTENE (ACNE) FOAM 0.1%	90050027003930	Brand
ARAZLO	TAZAROTENE (ACNE) LOTION 0.045%	90050027004120	Brand
TAZAROTENE	TAZAROTENE (ACNE) FOAM 0.1%	90050027003930	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication or intolerance to BOTH of the following:

1.1.2.1 generic tazarotene

AND

1.1.2.2 One of the following:

- generic adapalene
- generic topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication or intolerance to BOTH of the following:

1.2.3.1 generic tazarotene

AND

1.2.3.2 One of the following:

- generic adapalene
- generic topical tretinoin or tretinoin microsphere

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Brand Tazorac	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZORAC	TAZAROTENE CREAM 0.05%	90250070003720	Brand
TAZORAC	TAZAROTENE CREAM 0.1%	90250070003730	Brand
TAZORAC	TAZAROTENE GEL 0.05%	90250070004020	Brand
TAZORAC	TAZAROTENE GEL 0.1%	90250070004030	Brand

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Both of the following:

2.1 Trial and failure (of a minimum 30-day supply) within the past 180 days, or intolerance to generic tazarotene

AND

2.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one medium to high potency topical corticosteroid (e.g., triamcinolone, fluocinonide)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Generic tazarotene 0.1% cream, Generic tazarotene 0.05% cream, generic tazarotene 0.1% gel, generic tazarotene 0.05% gel	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZAROTENE	TAZAROTENE CREAM 0.1%	90250070003730	Generic
TAZAROTENE	TAZAROTENE GEL 0.05%	90250070004020	Generic
TAZAROTENE	TAZAROTENE GEL 0.1%	90250070004030	Generic
TAZAROTENE	TAZAROTENE CREAM 0.05%	90250070003720	Generic

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one medium to high potency topical corticosteroid (e.g., triamcinolone, fluocinonide)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Generic tazarotene 0.1% cream, generic tazarotene 0.1% gel	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TAZAROTENE	TAZAROTENE CREAM 0.1%	90250070003730	Generic
TAZAROTENE	TAZAROTENE GEL 0.1%	90250070004030	Generic

Approval Criteria

1 - One of the following:

1.1 Patient is 25 years of age or younger

OR

1.2 Both of the following:

- Patient is older than 25 years of age
- Diagnosis of acne vulgaris (i.e., acne)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

3 . Background

Clinical Practice Guidelines

Table 1. The use of topical retinoids for the following conditions was clarified as either medical or cosmetic (plan exclusions) [10]

Uses	Medical vs. Cosmetic
Actinic keratosis	Medical
Alopecia areata	Medical
Chloasma	Cosmetic
Fine wrinkles on face	Cosmetic
Hyperkeratosis	Medical
Hyperpigmentation of skin, Facial mottling	Cosmetic
Keloid scar	Medical
Roughness of skin, Facial tactile roughness	Cosmetic
Systematized epidermal nevus	Medical
Ultraviolet-induced change in normal skin	Cosmetic

Wound healing (mild)	Medical

Table 2. Relative potencies of topical corticosteroids [14-15]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05

	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

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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5. Avita Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. January 2018.

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12. Tazorac Prescribing Information. Allergan, Inc. Irvine, CA. July 2017.
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Prior Authorization Guideline

Guideline ID	GL-160975
Guideline Name	Trastuzumab - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Herceptin (trastuzumab), 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, 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

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, 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

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, 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

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

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

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, Herzuma, Ogivri, Ontruzant	
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

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.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160976
Guideline Name	Tremfya (guselkumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tremfya SC (guselkumab)
Plaque Psoriasis (PsO) Indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis. **Ulcerative Colitis (UC)** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.
Drug Name: Tremfya IV (guselkumab)
Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

2 . Criteria

Product Name: Tremfya SC 100 mg	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand

Approval Criteria

1 - Diagnosis of moderate-to-severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Tremfya SC 100 mg	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Tremfya SC 100 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Tremfya SC 100 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Tremfya IV	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB IV SOLN 200 MG/20ML (10 MG/ML)	90250542002030	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

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	9025054200D540	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 200 MG/2ML	9025054200E540	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Tremfya SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 100 MG/ML	9025054200D520	Brand
TREMFYA	GUSELKUMAB SOLN AUTO-INJECTOR 200 MG/2ML	9025054200D540	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML	9025054200E520	Brand
TREMFYA	GUSELKUMAB SOLN PREFILLED SYRINGE 200 MG/2ML	9025054200E540	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5, 6]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

3 . References

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160977
Guideline Name	Tukysa (tucatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tukysa (tucatinib)
Breast Cancer Indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. **Colorectal cancer** Indicated in combination with trastuzumab for the treatment of adult patients with RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2 . Criteria

Product Name: Tukysa	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TUKYSA	TUCATINIB TAB 50 MG	21170080000320	Brand
TUKYSA	TUCATINIB TAB 150 MG	21170080000340	Brand

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

- Advanced unresectable
- Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Used in combination with trastuzumab and capecitabine

AND

5 - Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine)

Product Name: Tukysa	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TUKYSA	TUCATINIB TAB 50 MG	21170080000320	Brand
TUKYSA	TUCATINIB TAB 150 MG	21170080000340	Brand

Approval Criteria

1 - Diagnosis of colorectal cancer

AND

2 - Disease is one of the following:

- Unresectable
- Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Patient has RAS wild-type tumors

AND

5 - Used in combination with trastuzumab

AND

6 - Patient has progressed following treatment with ONE of the following:

- Fluoropyrimidine-based chemotherapy
- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy

Product Name: Tukysa	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TUKYSA	TUCATINIB TAB 50 MG	21170080000320	Brand
TUKYSA	TUCATINIB TAB 150 MG	21170080000340	Brand
TUKYSA	TUCATINIB TAB 50 MG	21170080000320	Brand
TUKYSA	TUCATINIB TAB 150 MG	21170080000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Tukysa Prescribing Information. Seattle Genetics, Inc. Bothell, WA. January 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160978
Guideline Name	Turalio (pexidartinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Turalio (pexidartinib)
Tenosynovial Giant Cell Tumor (TGCT) Indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

2 . Criteria

Product Name: Turalio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TURALIO	PEXIDARTINIB HCL CAP 200 MG (BASE EQUIVALENT)	21533045010120	Brand
TURALIO	PEXIDARTINIB HCL CAP 125 MG (BASE EQUIVALENT)	21533045010110	Brand

Approval Criteria

1 - Diagnosis of tenosynovial giant cell tumor (TGCT)

AND

2 - Patient is symptomatic

AND

3 - Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal

Product Name: Turalio	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TURALIO	PEXIDARTINIB HCL CAP 200 MG (BASE EQUIVALENT)	21533045010120	Brand
TURALIO	PEXIDARTINIB HCL CAP 125 MG (BASE EQUIVALENT)	21533045010110	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Turalio prescribing information. Daiichi Sankyo, Inc. Basking Ridge, NJ. November 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160979
Guideline Name	Tykerb (lapatinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tykerb (lapatinib)
Metastatic breast cancer (1) In combination with Xeloda (capecitabine), indicated for the treatment of patients with advanced or metastatic breast cancer whose tumors over-express HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. Limitations of use: Patients should have disease progression on trastuzumab prior to initiation of treatment with Tykerb in combination with capecitabine.; (2) In combination with Femara (letrozole), indicated for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated. Tykerb in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer. **Off Label Uses: HER2-positive Breast Cancer [4-6]** Used for the first-line treatment of HER2-positive locally-advanced or metastatic breast cancer.

2 . Criteria

Product Name: Brand Tykerb, generic lapatinib	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LAPATINIB DITOSYLATE	LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)	21533026100320	Generic
TYKERB	LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)	21533026100320	Brand

Approval Criteria

1 - Diagnosis of HER2-positive metastatic or recurrent breast cancer [2-6]

AND

2 - Used in combination with one of the following: [3]

- Trastuzumab
- Xeloda (capecitabine)
- Aromatase inhibitors [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

Product Name: Brand Tykerb, generic lapatinib	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
LAPATINIB DITOSYLATE	LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)	21533026100320	Generic
TYKERB	LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)	21533026100320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease

3 . References

1. Tykerb Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. March 2022.
2. Geyer CE, Forster J, Lindquist D, et al. Lapatinib plus capecitabine for HER2-positive advanced breast cancer. N Engl J Med. 2006;355(26):2733-2743.
3. National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium. National Comprehensive Cancer Network, Inc. 2020. Accessed August 26, 2022.
4. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed August 12, 2020.
5. Moy B, Goss PE. Lapatinib: current status and future directions in breast cancer. Oncologist. 2006;11:1047-57.
6. Gomez H, Doval D, Chavez M, et al. Efficacy and safety of lapatinib as first-line therapy for ErbB2-amplified locally advanced or metastatic breast cancer. J Clin Oncol. 2008 May 5 [Epub ahead of print].
7. Lapatinib Prescribing Information. Lupin Pharmaceuticals, Inc. Baltimore, MD. November 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160980
Guideline Name	Tysabri (natalizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Tysabri (natalizumab)
Multiple Sclerosis (MS) Indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with Tysabri, physicians should consider whether the expected benefit of Tysabri is sufficient to offset this risk. **Crohn's Disease (CD)** Indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active CD with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha. In CD, Tysabri should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-alpha.

2 . Criteria

Product Name: Tysabri	
Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYSABRI	NATALIZUMAB FOR IV INJ CONC 300 MG/15ML	62405050001320	Brand

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [B]

AND

2 - One of the following:

2.1 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

OR

2.2 Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their multiple sclerosis [2]

OR

2.3 For continuation of prior therapy [2]

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Tysabri	
Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYSABRI	NATALIZUMAB FOR IV INJ CONC 300 MG/15ML	62405050001320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Tysabri

Diagnosis	Crohn’s Disease (CD)
Approval Length	3 Months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYSABRI	NATALIZUMAB FOR IV INJ CONC 300 MG/15ML	62405050001320	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Crohn's disease has evidence of inflammation (e.g., elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes) [1,3]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [3, 7]:

- corticosteroids (e.g., prednisone)
- 6-mercaptopurine
- azathioprine
- methotrexate

AND

4 - Trial and failure, contraindication, or intolerance to a tumor necrosis factor (TNF)-inhibitor (e.g., certolizumab pegol, adalimumab)

AND

5 - Not used in combination with TNF inhibitors (e.g., certolizumab pegol, adalimumab) or immunosuppressants (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name: Tysabri	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TYSABRI	NATALIZUMAB FOR IV INJ CONC 300 MG/15ML	62405050001320	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 3, 7]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND

2 - Not used in combination with TNF inhibitors (e.g., certolizumab pegol, adalimumab) or immunosuppressants (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

3 . Endnotes

A. To minimize the risk of progressive multifocal leukoencephalopathy, natalizumab must be administered as a monotherapy without concomitant immunosuppressive therapy. Aminosalicylates may be continued during treatment with Tysabri. [1, 3]
B. Of the four disease courses of MS, relapse-remitting MS (RRMS) is characterized primarily by relapse, while secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. Most patients with RRMS eventually develop SPMS. As a person transitions from RRMS to SPMS, the disease begins to worsen more steadily, with or without occasional relapses, slight remissions, or plateaus. As long as the patient continues to have relapses, the SPMS course is considered to be both progressive and relapsing. [4]
C. In the postmarketing setting, additional cases of PML have been reported in multiple sclerosis and Crohn's disease patients who were receiving no concomitant immunomodulatory therapy. Three factors that are known to increase the risk of PML in Tysabri-treated patients have been identified: 1) Longer treatment duration, especially beyond 2 years. 2) Prior treatment with an immunosuppressant (e.g., mitoxantrone, azathioprine, methotrexate, cyclophosphamide, mycophenolate mofetil). 3) The presence of anti-JCV antibodies. Patients who are anti-JCV antibody positive have a higher risk for developing PML. [1]
D. Tysabri should be discontinued in patients with Crohn's disease who have not experienced therapeutic benefit by 12 weeks of induction therapy. For patients with Crohn's disease who start Tysabri while on chronic oral corticosteroids, steroid tapering should begin as soon as a therapeutic benefit of Tysabri has occurred. Tysabri should be discontinued if patients cannot be tapered off of oral corticosteroids within six months of starting Tysabri. Other than the initial six-month taper, prescribers should consider discontinuing Tysabri for patients who require additional steroid use that exceeds three months in a calendar year to control their Crohn's disease. [1]

4 . References

1. Tysabri Prescribing Information. Biogen Inc. Cambridge, MA. October 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. Lichtenstein GR, Loftus EV, Isaacs KL, et al. Management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
4. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed April 11, 2022.
5. FDA Drug Safety Communication: New risk factor for progressive multifocal leukoencephalopathy (PML) associated with Tysabri (natalizumab). January 20, 2012. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm288186.htm. Accessed April 11, 2022.
6. Nelson SML, Nguyen TM, McDonald J, MacDonald JK. Natalizumab for induction of remission in Crohn's disease. Cochrane Database of Systematic Reviews 2018, Issue 8. Art. No.: CD006097. DOI: 10.1002/14651858.CD006097.pub3.
7. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160981
Guideline Name	Ultomiris (ravulizumab-cwvz)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Ultomiris (ravulizumab-cwvz)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH). **Atypical Hemolytic Uremic Syndrome (aHUS)** Indicated for the treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA). Limitations of Use: Ultomiris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). **Generalized Myasthenia Gravis (gMG)** Indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive. **Neuromyelitis Optica Spectrum Disorder** Indicated for the treatment of adult patients with

neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS) [1]

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist
- Nephrologist

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., normalization of platelet count, improvement in serum creatinine from baseline) to therapy

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand

ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following: [2]

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Ultomiris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Ophthalmologist

Product Name: Ultomiris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 300 MG/3ML (100 MG/ML)	85805080202045	Brand
ULTOMIRIS	RAVULIZUMAB-CWVZ IV SOLN 1100 MG/11ML (100 MG/ML)	85805080202060	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

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.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160982
Guideline Name	Venclexta (venetoclax)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Venclexta (venetoclax)
Chronic lymphocytic leukemia or Small lymphocytic lymphoma Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). **Acute Myeloid Leukemia** Indicated in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

2 . Criteria

Product Name: Venclexta	
Diagnosis	Chronic lymphocytic leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VENCLEXTA STARTING PACK	VENETOCLAX TAB THERAPY STARTER PACK 10 & 50 & 100 MG	2147008000B720	Brand
VENCLEXTA	VENETOCLAX TAB 10 MG	21470080000320	Brand
VENCLEXTA	VENETOCLAX TAB 50 MG	21470080000340	Brand
VENCLEXTA	VENETOCLAX TAB 100 MG	21470080000360	Brand

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

Product Name: Venclexta	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VENCLEXTA STARTING PACK	VENETOCLAX TAB THERAPY STARTER PACK 10 & 50 & 100 MG	2147008000B720	Brand
VENCLEXTA	VENETOCLAX TAB 10 MG	21470080000320	Brand
VENCLEXTA	VENETOCLAX TAB 50 MG	21470080000340	Brand
VENCLEXTA	VENETOCLAX TAB 100 MG	21470080000360	Brand

Approval Criteria

1 - Diagnosis of AML

AND

2 - Disease is one of the following: [3]

- Newly diagnosed
- Relapsed
- Refractory

Product Name: Venclexta	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VENCLEXTA STARTING PACK	VENETOCLAX TAB THERAPY STARTER PACK 10 & 50 & 100 MG	2147008000B720	Brand
VENCLEXTA	VENETOCLAX TAB 10 MG	21470080000320	Brand
VENCLEXTA	VENETOCLAX TAB 50 MG	21470080000340	Brand
VENCLEXTA	VENETOCLAX TAB 100 MG	21470080000360	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Venclexta Prescribing Information. AbbVie, Inc. North Chicago, IL. June 2022.
2. National comprehensive cancer network (NCCN) clinical practice guidelines in oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma. v.5.2019. Available from: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed June 4, 2019.

3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on September 7, 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160983
Guideline Name	Veopoz (pozelimab-bbfg)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160984
Guideline Name	Verzenio (abemaciclib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Verzenio (abemaciclib)
Advanced or Metastatic Breast Cancer Indicated in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. **Advanced or Metastatic Breast Cancer** Indicated as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting. **Advanced or Metastatic Breast Cancer** Indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer. **Early Breast Cancer** Indicated in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-

positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence.

2 . Criteria

Product Name: Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VERZENIO	ABEMACICLIB TAB 50 MG	21531010000305	Brand
VERZENIO	ABEMACICLIB TAB 100 MG	21531010000310	Brand
VERZENIO	ABEMACICLIB TAB 150 MG	21531010000315	Brand
VERZENIO	ABEMACICLIB TAB 200 MG	21531010000320	Brand

Approval Criteria

1 - Diagnosis of breast cancer

Product Name: Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VERZENIO	ABEMACICLIB TAB 50 MG	21531010000305	Brand
VERZENIO	ABEMACICLIB TAB 100 MG	21531010000310	Brand

VERZENIO	ABEMACICLIB TAB 150 MG	21531010000315	Brand
VERZENIO	ABEMACICLIB TAB 200 MG	21531010000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Verzenio Prescribing Information. Lilly USA, LLC. Indianapolis, IN. March 2023.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160985
Guideline Name	Votrient (pazopanib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Votrient (pazopanib)
Renal Cell Carcinoma (RCC) Indicated for the treatment of patients with advanced renal cell carcinoma (RCC). **Soft tissue sarcoma (STS)** Indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. Limitation of Use: The efficacy of Votrient for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors has not been demonstrated.

2 . Criteria

Product Name: Brand Votrient, Generic pazopanib

Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOTRIENT	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Brand
PAZOPANIB HYDROCHLORIDE	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Generic

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following: [2]

- Disease has relapsed
- Diagnosis of stage IV disease

AND

3 - Trial and failure, or intolerance to generic pazopanib (applies to brand Votrient only)

AND

4 - One of the following: [2]

4.1 One of the following:

4.1.1 Both of the following:

- Used in the treatment of non-clear cell renal cell carcinoma
- Trial and failure, contraindication or intolerance to generic sunitinib

OR

4.1.2 For continuation of prior therapy

OR

4.2 Patient has clear cell renal cell carcinoma

Product Name: Brand Votrient, Generic pazopanib	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOTRIENT	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Brand
PAZOPANIB HYDROCHLORIDE	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure, or intolerance to generic pazopanib (applies to brand Votrient only)

AND

3 - One of the following:

3.1 One of the following:

3.1.1 Both of the following:

- Used in the treatment of non-clear cell renal cell carcinoma
- Trial and failure, contraindication or intolerance to generic sunitinib

OR

3.1.2 For continuation of prior therapy

OR

3.2 Patient has clear cell renal cell carcinoma

Product Name: Brand Votrient, Generic pazopanib	
Diagnosis	Soft tissue sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOTRIENT	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Brand
PAZOPANIB HYDROCHLORIDE	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Generic

Approval Criteria

1 - Diagnosis of advanced soft tissue sarcoma (STS) [4, A]

AND

2 - Trial and failure, or intolerance to generic pazopanib (Applies to Brand Votrient only)

Product Name: Brand Votrient, Generic pazopanib	
Diagnosis	Soft tissue sarcoma (STS)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VOTRIENT	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Brand
PAZOPANIB HYDROCHLORIDE	PAZOPANIB HCL TAB 200 MG (BASE EQUIV)	21533042100320	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure, or intolerance to generic pazopanib (Applies to Brand Votrient only)

3 . Endnotes

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. December 2021.
2. National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Kidney cancer v.4.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed February 28, 2023.
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.2.2022. Available at: http://www.nccn.org/professionals/physician_gls/PDF/sarcoma.pdf. Accessed February 28, 2023.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160986
Guideline Name	Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)
Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) Indicated for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

2 . Criteria

Product Name: Vyndaqel, Vyndamax	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYNDAQEL	TAFAMIDIS MEGLUMINE (CARDIAC) CAP 20 MG	40550080200120	Brand
VYNDAMAX	TAFAMIDIS CAP 61 MG	40550080000120	Brand

Approval Criteria

1 - Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM)

AND

2 - One of the following: [3, 4]

2.1 Patient has a transthyretin (TTR) mutation (e.g., V122I)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits

OR

2.3 All of the following:

- Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis
- Scintigraphy scan suggestive of cardiac TTR amyloidosis
- Absence of light-chain amyloidosis

AND

3 - One of the following: [2]

- History of heart failure, with at least one prior hospitalization for heart failure
- Presence of clinical signs and symptoms of heart failure (e.g., dyspnea, edema)

AND

4 - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure [2]

AND

5 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Diflunisal)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Vyndaqel, Vyndamax	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
VYNDAQEL	TAFAMIDIS MEGLUMINE (CARDIAC) CAP 20 MG	40550080200120	Brand
VYNDAMAX	TAFAMIDIS CAP 61 MG	40550080000120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

3 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Diflunisal)

AND

4 - Prescribed by or in consultation with a cardiologist

3 . References

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
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160987
Guideline Name	Xalkori (crizotinib) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xalkori (crizotinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)- or ROS1-positive as detected by an FDA-approved test. **Anaplastic Large Cell Lymphoma (ALCL)** Indicated for the treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. Limitations of use: The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL. **Inflammatory Myofibroblastic Tumor** Indicated for the treatment of adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive.

2 . Criteria

Product Name: Xalkori	
Diagnosis	Non-small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

2.1.2 One of the following:

2.1.2.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

- Alecensa (alectinib)
- Alunbrig (brugatinib)

OR

2.1.2.2 For continuation of therapy

OR

2.2 Patient has ROS1 rearrangements-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma (ALCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Diagnosis of systemic anaplastic large cell lymphoma (ALCL)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient is 1 year of age or older

AND

4 - Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

2 - Disease is one of the following:

- Unresectable
- Recurrent
- Refractory

AND

3 - Patient is 1 year of age or older

AND

4 - Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Xalkori	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Xalkori	
Diagnosis	Non-small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Both of the following:

2.1.1 Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

2.1.2 One of the following:

2.1.2.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

- Alecensa (alectinib)
- Alunbrig (brugatinib)

OR

2.1.2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

OR

2.2 Patient has ROS1 rearrangements-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma (ALCL)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of systemic anaplastic large cell lymphoma (ALCL)

AND

1.2 Disease is one of the following:

- Relapsed
- Refractory

AND

2 - Patient is 1 year of age or older

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XALKORI	CRIZOTINIB CAP 200 MG	21530517000120	Brand
XALKORI	CRIZOTINIB CAP 250 MG	21530517000125	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 20 MG	21530517006820	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 50 MG	21530517006830	Brand
XALKORI	CRIZOTINIB CAP SPRINKLE 150 MG	21530517006850	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

1.2 Disease is one of the following:

- Unresectable
- Recurrent
- Refractory

AND

2 - Patient is 1 year of age or older

AND

3 - Submission of medical records (e.g., chart notes) confirming the patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

3 . References

1. Xalkori Prescribing Information. Pfizer Labs. New York, NY. September 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed August 12, 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160988
Guideline Name	Xdemvy (lotilaner) PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xdemvy (lotilaner ophthalmic solution)
Demodex Blepharitis Indicated for the treatment of Demodex blepharitis.

2 . Criteria

Product Name: Xdemvy	
Approval Length	2 months [A, 3]
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XDEMVY	LOTILANER OPHTH SOLN 0.25%	86106050002020	Brand

Approval Criteria

1 - Diagnosis of Demodex blepharitis

AND

2 - Patient exhibits one of the following signs of Demodex infestation [2]

- Collarettes [B, 2]
- Eyelid margin erythema
- Eyelash anomalies (e.g., eyelash misdirection)

AND

3 - Patient is experiencing symptoms or architectural changes associated with Demodex infestation (e.g., burning, tearing, itching, foreign body sensation, eyelashes missing, eyelashes growing inward) [C, 3]

AND

4 - Trial and inadequate response to tea tree-oil [D-E, 3-4]

AND

5 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

Product Name: Xdemvy

Approval Length	2 months [A, 3]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XDEMVY	LOTILANER OPHTH SOLN 0.25%	86106050002020	Brand

Approval Criteria

1 - Diagnosis of Demodex blepharitis

AND

2 - Submission of medical records (e.g., chart notes) confirming that patient exhibits one of the following signs of Demodex infestation confirmed by slit lamp examination [F-H, 2, 7-9]

- Collarettes [B, 2]
- Eyelid margin erythema
- Eyelash anomalies (e.g., eyelash misdirection)

AND

3 - Submission of medical records (e.g., chart notes) confirming that patient is experiencing symptoms or architectural changes associated with Demodex infestation (e.g., burning, tearing, itching, foreign body sensation, eyelashes missing, eyelashes growing inward) [C, 3]

AND

4 - Submission of medical records (e.g., chart notes) confirming trial and inadequate response (minimum 6 weeks) to tea tree-oil [D-E, I, 3-4, 10-11]

AND

5 - Symptoms persist despite practicing good eye-lid hygiene (e.g.,treatment with warm compress, eyelid cleansing, artificial tears, non-prescription tree-tea oil)

AND

6 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

3 . Definitions

Definition	Description
Collarettes	Solidified exudative excretions that form a cylindrical collar around the base of the eyelash follicle - are the pathognomonic sign of Demodex blepharitis [2].

4 . Endnotes

A. Xdemvy kills the "adult" mite. However, the product does not kill the eggs. The life cycle of the mite is about 27 days. The eggs will hatch. If stop prior to this, those 2nd generation mites won't be killed. Need 2 or 3 generations to eradicate mites and eggs that will hatch. Multiple courses of treatment may be necessary. The physician would re-evaluate patient after 3 months not 6 weeks. Goal of treatment is to get to a threshold below where the patient is not experiencing symptoms. Mites live on clothes, pillowcases, sheets so re-infection possible. For this reason, difficult to eradicate to where there are "zero" mites.[3]
B. Collarettes are often referred to in the literature as cylindrical dandruff (CD), sleeves, cuffs, crusting, or lash debris [2]
C. If Demodex is not overpopulated and not causing problem can leave it alone; if burning, tearing, itching, foreign body sensation, etc. or architectural changes in lid, eyelashes missing, eyelashes grow inward (scratching cornea, scarring), consider treating the Demodex blepharitis [3]
D. Tea Tree Oil has been the standard treatment. It suppresses the mite and tricks the mite into coming out of its buried status in the skin. Mites are nocturnal, so they are embedded during the day and come out at night. Tea tree oil is available in shampoos, soaps, and specific ocular products (e.g., Cliradex 10% wipes or foam) and are available OTC. Cliradex 50% is available and is used as an in office procedure since higher concentrations can be very irritating to the eyes and skin [3]

E. In general, topical formulations containing tea tree oil were reported to be effective in reducing the number of Demodex mites on eyelashes. Other emerging treatment options include anti-parasitic drugs and IPL, but there is currently limited high-quality evidence to ascertain the efficacy of these treatments for ocular Demodex with any certainty. [4]
F. Because patients with Demodex blepharitis can often be asymptomatic, it is important to begin every clinical evaluation at the slit lamp with the patient's eyes closed for a better view of the superior lid and lash margin, looking for the presence of collarettes. [7]
G. Slit-lamp examination is all an eye care provider needs to do to make the diagnosis [8]
H. Several conditions such as rosacea, MGD, and DED often occur with DB [52–55]. Since clinically these conditions are often very similar, the panel concurred that DB is frequently underdiagnosed or misdiagnosed. The consensus, therefore, was that all patients presenting for an eye exam should be evaluated for collarettes, especially those with lid abnormalities or those not responding to treatment for DED or MGD. DEPTH panellists shared that slit lamp examination with the patient looking down is simple and easy to incorporate into routine exams. [9]
I. It has been recommended to use tea tree oil treatments for at least two Demodex mite life cycles (i.e. approximately six weeks) in order to ensure adequate killing of the parasite [10]

5 . References

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6 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160989
Guideline Name	Xeljanz, Xeljanz XR (tofacitinib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xeljanz (tofacitinib) tablets, Xeljanz XR (tofacitinib) extended-release tablets
Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not

recommended.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis, who have an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Drug Name: Xeljanz (tofacitinib) tablets and oral solution

Polyarticular Course Juvenile Idiopathic Arthritis Indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

2 . Criteria

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT)	66603065102020	Brand

Approval Criteria

1 - Diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, etanercept)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT)	66603065102020	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand

XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 6]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	4 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand

XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT)	66603065107550	Brand

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [7, 8]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, golimumab)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XELJANZ	TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)	66603065100320	Brand
XELJANZ	TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)	66603065100330	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT)	66603065107530	Brand
XELJANZ XR	TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT)	66603065107550	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 7, 8]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND **2** - Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*	
Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Endnotes

A. Initial approval length of 4 months based on dosing recommendation provided in the labeling of Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily for at least 8 weeks, followed by Xeljanz 5 mg once or twice daily, 10 mg twice daily, or Xeljanz XR 11 mg once daily depending on therapeutic response. Xeljanz should be discontinued after 16 weeks (4 months) of treatment with Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily if adequate therapeutic response is not achieved.

4 . References

1. Xeljanz, Xeljanz XR Prescribing Information. Pfizer, Inc. New York, NY. May 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.
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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. 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.
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5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160990
Guideline Name	Xenazine (tetrabenazine)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xenazine (tetrabenazine)
Chorea associated with Huntington's disease Indicated for the treatment of chorea associated with Huntington's disease. **Off Label Uses: Hyperkinetic movement disorders in tardive dyskinesia and Tourette's syndrome [2-5]** Has shown effectiveness in the treatment of hyperkinetic movement disorders (hyperkinesias) characterized by abnormal involuntary movements seen in tardive dyskinesia (TD), or issues such as tics (eye blink, shouting obscenities or profanities, etc.) observed in Tourette's syndrome (TS).

2 . Criteria

Product Name: Brand Xenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

AND

2 - Prescribed by or in consultation with a neurologist [C]

AND

3 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name: Generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

AND

2 - Prescribed by or in consultation with a neurologist [C]

Product Name: Brand Xenazine, Generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Brand Xenazine	
Diagnosis	Tourette's syndrome (Off-label)
Approval Length	3 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome [2, 4]

AND

2 - Trial and failure, contraindication, or intolerance to a minimum 30 day supply of Haldol (haloperidol)

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

AND

4 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name: Generic tetrabenazine	
Diagnosis	Tourette's syndrome (Off-label)
Approval Length	3 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome [2, 4]

AND

2 - Trial and failure, contraindication, or intolerance to a minimum 30 day supply of Haldol (haloperidol)

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Brand Xenazine, Generic tetrabenazine	
Diagnosis	Tourette's syndrome (Off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Brand Xenazine	
Diagnosis	Tardive dyskinesia (Off-label)
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand

Approval Criteria

1 - Diagnosis of tardive dyskinesia [3, 4]

AND

2 - One of the following [A, 5]:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

AND

4 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name: Generic tetrabenazine	
Diagnosis	Tardive dyskinesia (Off-label)
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Diagnosis of tardive dyskinesia [3, 4]

AND

2 - One of the following [A, 5]:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Brand Xenazine, Generic tetrabenazine	
Diagnosis	Tardive dyskinesia (Off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Brand
XENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Brand
TETRABENAZINE	TETRABENAZINE TAB 12.5 MG	62380070000310	Generic
TETRABENAZINE	TETRABENAZINE TAB 25 MG	62380070000320	Generic

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. Verified with consultant for a previous medication (Ingrezza [valbenazine]) that dose reduction, tapering, or discontinuation of the offending medication is considered first-line treatment for tardive dyskinesia. [5]
B. Authorization period is based on the pivotal study duration of 12 weeks. [1]
C. Ensures the requirement for proper diagnosing and quantifying an adequate chorea score (total maximal chorea score of greater than or equal to 10 (moderate to severe chorea) from the subscale of the Unified Huntington's Disease Rating Scale (UHDRS). Note that the pivotal trial that established efficacy of tetrabenazine included patients with a total maximal chorea of greater than or equal to 10. [1]

4 . References

1. Xenazine Prescribing Information. Lundbeck. Deerfield, IL. November 2019.
2. Sweet RD, Brauun R, Shapiro E, Shapiro AK. Presynaptic catecholamine antagonists as treatment for Tourette syndrome. Effects of alpha methyl para tyrosine and tetrabenazine. Arch Gen Psych. 1974;31:857-861.
3. Kazamatsuri H, Chien C-P, Cole J. Treatment of Tardive Dyskinesia: clinical efficacy of a dopamine-depleting agent, tetrabenazine. Arch Gen Psychiat. 1972;27:95-99.

4. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at: https://www.micromedexsolutions.com. Accessed April 1, 2021.
5. Per clinical consult with psychiatrist regarding Ingrezza (valbenazine), June 9, 2017.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160991
Guideline Name	Xgeva (denosumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xgeva (denosumab)
Multiple myeloma and Bone metastasis from solid tumors Indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. **Giant cell tumor of bone** Indicated for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. **Hypercalcemia of malignancy** Indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

2 . Criteria

Product Name: Xgeva	
Diagnosis	Skeletal prevention in multiple myeloma and bone metastasis from solid tumors (BMST)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XGEVA	DENOSUMAB INJ 120 MG/1.7ML	30044530002030	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of multiple myeloma

AND

1.1.2 Trial and failure, contraindication (e.g., renal insufficiency), or intolerance, to one intravenous bisphosphonate (e.g., zoledronic acid) [9]

OR

1.2 Both of the following:

1.2.1 Diagnosis of solid tumors (e.g., breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) [1-5]

AND

1.2.2 Documented evidence of one or more metastatic bone lesions

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Xgeva	
Diagnosis	Giant cell tumor of bone
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XGEVA	DENOSUMAB INJ 120 MG/1.7ML	30044530002030	Brand

Approval Criteria

1 - Diagnosis of giant cell tumor of bone

AND

2 - One of the following:

2.1 Tumor is unresectable

OR

2.2 Surgical resection is likely to result in severe morbidity

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Xgeva	
Diagnosis	Giant cell tumor of bone
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XGEVA	DENOSUMAB INJ 120 MG/1.7ML	30044530002030	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xgeva therapy [A]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Xgeva	
Diagnosis	Hypercalcemia of malignancy
Approval Length	2 Month [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XGEVA	DENOSUMAB INJ 120 MG/1.7ML	30044530002030	Brand

Approval Criteria

1 - Diagnosis of hypercalcemia of malignancy

AND

2 - Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (e.g., pamidronate, zoledronic acid) [6, 7]

Notes	If patient meets criteria above, please approve at GPI-12.

Product Name: Xgeva	
Diagnosis	Hypercalcemia of malignancy
Approval Length	2 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

XGEVA	DENOSUMAB INJ 120 MG/1.7ML	30044530002030	Brand

Approval Criteria

1 - Documentation of positive clinical response to Xgeva therapy

Notes	If patient meets criteria above, please approve at GPI-12.

3 . Endnotes

A. Xgeva should be continued until disease progression in responding patients. [8]
B. Median time on the study for the treatment of hypercalcemia of malignancy was 56 days. [6]

4 . References

1. Xgeva prescribing information. Amgen Inc. Thousand Oaks, CA. June 2020.
2. Stopeck AT, Lipton A, Body JJ, et al. Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer: a randomized, double-blind study. J Clin Oncol. 2010;28:5132-39.
3. Fizazi K, Carducci MA, Smith MR, et al. Denosumab versus zoledronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: a randomised, double-blind study. Lancet. 2011;377(9768):813-22.
4. Henry DH, Costa L, Goldwasser F, et al. Randomized, double-blind study of denosumab versus zoledronic acid in the treatment of bone metastases in patients with advanced cancer (excluding breast and prostate cancer) or multiple myeloma. J Clin Oncol. 2011;29(9):1125-32.
5. Lipton A, Fizazi K, Stopeck AT, Henry DH, et al. Superiority of denosumab to zoledronic acid for prevention of skeletal-related events: a combined analysis of 3 pivotal, randomised, phase 3 trials. Eur J Cancer. 2012;48(16):3082-92.
6. Hu MI, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocinol Metab. 2014;99(9):3144-52.
7. Stewart AF. Hypercalcemia associated with cancer. N Engl J Med. 2005; 352(4):379-9.
8. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Bone Cancer v1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed June 9, 2021.
9. National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 2, 2022.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160992
Guideline Name	Xiaflex (collagenase clostridium histolyticum)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xiaflex (collagenase clostridium histolyticum)
Dupuytren's Contracture Indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord. **Peyronie's Disease** Indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

2 . Criteria

Product Name: Xiaflex	
Diagnosis	Dupuytren’s contracture

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIAFLEX	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM FOR INJ 0.9 MG	99350035002120	Brand

Approval Criteria

1 - Diagnosis of Dupuytren's contracture with a palpable cord

AND

2 - Patient has a positive "table top test" (defined as the inability to simultaneously place the affected finger and palm flat against a table top) [A]

AND

3 - Patient has a documented contracture of at least 20 degrees flexion for a metacarpophalangeal joint or a proximal interphalangeal joint [B]

AND

4 - Patient has a flexion deformity that results in functional limitations

Product Name: Xiaflex	
Diagnosis	Peyronie's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIAFLEX	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM FOR INJ 0.9 MG	99350035002120	Brand

Approval Criteria

1 - Diagnosis of Peyronie's disease

AND

2 - Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy [C]

AND

3 - The plaques do not involve the penile urethra

AND

4 - Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse) [C]

Product Name: Xiaflex	
Diagnosis	Peyronie's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIAFLEX	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM FOR INJ 0.9 MG	99350035002120	Brand

Approval Criteria

1 - Diagnosis of Peyronie's disease

AND

2 - Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

AND

3 - The plaques do not involve the penile urethra

AND

4 - Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse)

AND

5 - Patient has a new plaque that results in a curvature deformity

3 . Endnotes

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. July 2022.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160773
Guideline Name	Xifaxan (rifaximin) - PA, NF
Formulary	• Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xifaxan (rifaximin)
Travelers' Diarrhea 200mg is indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adults and pediatric patients 12 years of age and older. Limitations of use: Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli. [A] **Prophylaxis of Hepatic Encephalopathy Recurrence** 550 mg is indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults. In the trials of Xifaxan for HE, 91% of patients were using lactulose concomitantly. Differences in the treatment effect of those patients not using lactulose concomitantly could not be assessed. Xifaxan has not been studied in patients with MELD (Model for End-Stage Liver Disease) score greater than 25, and only 8.6% of patients in the controlled trial had MELD scores over 19. There is increased systemic exposure in patients with more severe hepatic dysfunction. **Irritable Bowel Syndrome with Diarrhea** 550 mg is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults. **Off Label Uses: Treatment of Hepatic Encephalopathy** Used for the treatment of hepatic encephalopathy. [4, 5, 22]

Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)
Has been used for the treatment of small intestinal bacterial overgrowth. [7, 8, 10, 13]

2 . Criteria

Product Name: Xifaxan 200 mg tablets*	
Diagnosis	Travelers' Diarrhea (TD)
Approval Length	1 Time only
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand

Approval Criteria

1 - Diagnosis of travelers' diarrhea (TD)

AND

2 - Disease is moderate to severe [D, 9]

AND

3 - One of the following:

3.1 Trial and failure of one of the following: [2, 3, D, E]

- Zithromax (azithromycin)
- Cipro (ciprofloxacin)
- Levaquin (levofloxacin)
- Ofloxacin

OR

3.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

- Zithromax (azithromycin)
- Cipro (ciprofloxacin)
- Levaquin (levofloxacin)
- Ofloxacin

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name: Xifaxan 200 mg tablets*	
Diagnosis	Travelers' Diarrhea (TD)
Approval Length	1 Time only
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of travelers' diarrhea (TD)

AND

2 - Disease is moderate to severe [D, 9]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Trial and failure to two of the following: [2, 3, D, E]

- Zithromax (azithromycin)
- Cipro (ciprofloxacin)
- Levaquin (levofloxacin)
- Ofloxacin

OR

3.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

- Zithromax (azithromycin)
- Cipro (ciprofloxacin)
- Levaquin (levofloxacin)
- Ofloxacin

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name: Xifaxan	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Diagnosis of Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)

AND

2 - One of the following:

2.1 Trial and failure of two of the following antibiotics: [5, 16-21]

- Neomycin
- Augmentin (amoxicillin/clavulanic acid)
- Cipro (ciprofloxacin)
- Bactrim (trimethoprim-sulfamethoxazole)
- Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline
- Flagyl (metronidazole)
- Keflex (cephalexin)

OR

2.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

- Neomycin
- Augmentin (amoxicillin/clavulanic acid)
- Cipro (ciprofloxacin)
- Bactrim (trimethoprim-sulfamethoxazole)
- Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline
- Flagyl (metronidazole)
- Keflex (cephalexin)

Product Name: Xifaxan	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., resolution of symptoms or relapse with Xifaxan discontinuation) [B]

AND

2 - One of the following:

2.1 Trial and failure of two of the following antibiotics: [5, 16-21]

- Neomycin
- Augmentin (amoxicillin/clavulanic acid)
- Cipro (ciprofloxacin)
- Bactrim (trimethoprim-sulfamethoxazole)
- Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline
- Flagyl (metronidazole)
- Keflex (cephalexin)

OR

2.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

- Neomycin
- Augmentin (amoxicillin/clavulanic acid)
- Cipro (ciprofloxacin)
- Bactrim (trimethoprim-sulfamethoxazole)
- Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline
- Flagyl (metronidazole)
- Keflex (cephalexin)

Product Name: Xifaxan 200 mg tablets*	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Trial and failure of three of the following antibiotics: [5, 16-21]

- Neomycin
- Augmentin (amoxicillin/clavulanic acid)
- Cipro (ciprofloxacin)
- Bactrim (trimethoprim-sulfamethoxazole)
- Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline
- Flagyl (metronidazole)
- Keflex (cephalexin)

OR

2.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

- Neomycin
- Augmentin (amoxicillin/clavulanic acid)
- Cipro (ciprofloxacin)
- Bactrim (trimethoprim-sulfamethoxazole)
- Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline
- Flagyl (metronidazole)
- Keflex (cephalexin)

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name: Xifaxan 550 mg tablets*	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	2 Weeks [1, I]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) [F]

AND

2 - Patient is 18 years of age or older [L]

AND

3 - Trial and failure, contraindication, or intolerance to both of the following:

- A Tricyclic Antidepressant (e.g., amitriptyline, nortriptyline)
- Viberzi

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name: Xifaxan 550 mg tablets*	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	2 Weeks [1, I]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Symptoms of Irritable Bowel Syndrome continue to persist [G, H]

AND

2 - Patient demonstrates positive clinical response to therapy as evidenced by both of the following: [1]

- Improvement in abdominal pain
- Reduction in the Bristol Stool Scale

AND

3 - Trial and failure, contraindication, or intolerance to both of the following:

- A Tricyclic Antidepressant (e.g., amitriptyline, nortriptyline)
- Viberzi

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name: Xifaxan 550 mg tablets*	
Diagnosis	Prophylaxis of Hepatic Encephalopathy (HE) Recurrence
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Used for prophylaxis of hepatic encephalopathy (HE) recurrence

AND

2 - Patient is 18 years of age or older [L]

AND

3 - One of the following: [J, 22]

3.1 Both of the following:

3.1.1 Used as add-on therapy to lactulose

AND

3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

3.2 History of contraindication or intolerance to lactulose

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name: Xifaxan 550 mg tablets*	
Diagnosis	Prophylaxis of Hepatic Encephalopathy (HE) Recurrence
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy [M, 27, 28]

AND

2 - One of the following: [J, 22]

2.1 Both of the following:

2.1.1 Used as add-on therapy to lactulose

AND

2.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

2.2 History of contraindication or intolerance to lactulose

Notes	Note: *If patient meets criteria above, please approve at GPI-14.

Product Name: Xifaxan	
Diagnosis	Treatment of Hepatic Encephalopathy (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand
XIFAXAN	RIFAXIMIN TAB 550 MG	16000049000340	Brand

Approval Criteria

1 - Used for the treatment of hepatic encephalopathy (HE) [5, K]

AND

2 - Patient is 18 years of age or older [L]

AND

3 - One of the following: [22, K]

3.1 Both of the following:

3.1.1 Used as add-on therapy to lactulose

AND

3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

3.2 History of contraindication or intolerance to lactulose

Product Name: Xifaxan 200 mg tablets*	
Diagnosis	Treatment of Hepatic Encephalopathy (Off-Label)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
XIFAXAN	RIFAXIMIN TAB 200 MG	16000049000320	Brand

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming used for the treatment of hepatic encephalopathy (HE) [5, K]

AND

2 - Patient is 18 years of age or older [L]

AND **3** - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [22, K] **3.1** Both of the following: **3.1.1** Used as add-on therapy to lactulose **AND** **3.1.2** Patient is unable to achieve an optimal clinical response with lactulose monotherapy **OR** **3.2** History of contraindication or intolerance to lactulose	
Notes	Note: *If patient meets criteria above, please approve at GPI-14.

3 . Endnotes

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
11/18/2024	New Program

Prior Authorization Guideline

Guideline ID	GL-160993
Guideline Name	Xolair (omalizumab)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xolair (omalizumab)
Allergic Asthma Indicated for adults and pediatric patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Limitations of Use: Xolair is not indicated for treatment of other allergic conditions. Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus. **Chronic Spontaneous Urticaria (CSU)** Indicated for the treatment of adults and adolescents 12 years of age and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment. Limitations of Use: Xolair is not indicated for treatment of other forms of urticaria. **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** Indicated for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids. **IgE-Mediated Food Allergy** Indicated for the reduction of allergic reactions (Type I), including

anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy. XOLAIR is to be used in conjunction with food allergen avoidance. Limitations of Use: XOLAIR is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

2 . Criteria

Product Name: Xolair	
Diagnosis	Allergic Asthma
Approval Length	6 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Diagnosis of moderate to severe persistent allergic asthma [1, 2]

AND

2 - Positive skin test or in vitro reactivity to a perennial aeroallergen [1, D]

AND

3 - One of the following:

3.1 All of the following:

3.1.1 Patient is 6 years of age or older but less than 12 years of age

AND

3.1.2 Pre-treatment serum immunoglobulin (Ig)E level between 30 to 1300 IU/mL

AND

3.1.3 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications [3]:

3.1.3.1 Both of the following:

- Medium-dose inhaled corticosteroid (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

3.1.3.2 One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg])

OR

3.2 All of the following:

3.2.1 Patient is 12 years of age or older

AND

3.2.2 Pre-treatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL

AND

3.2.3 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications [3]:

3.2.3.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

3.2.3.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg])

AND

4 - Prescribed by or in consultation with one of the following: [G]

- Pulmonologist
- Allergist/Immunologist

Product Name: Xolair	
Diagnosis	Allergic Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications [3]

AND

3 - Prescribed by or in consultation with one of the following: [G]

- Pulmonologist
- Allergist/immunologist

Product Name: Xolair

Diagnosis	Chronic Spontaneous Urticaria (CSU)
Approval Length	3 months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Diagnosis of chronic spontaneous urticaria [1]

AND

2 - Patient is 12 years of age or older

AND

3 - Persistent symptoms (itching and hives) for at least 4 consecutive weeks despite titrating to an optimal dose with a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines

AND

4 - Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines

AND

5 - Patient has tried and had an inadequate response or intolerance at least TWO of the following additional therapies: [6, 7]

- Doxepin
- H1 antihistamine
- H2 antagonist (e.g., famotidine, cimetidine)
- Hydroxyzine
- Leukotriene receptor antagonist (e.g., montelukast)

AND

6 - Prescribed by or in consultation with one of the following:

- Allergist/immunologist
- Dermatologist

Product Name: Xolair	
Diagnosis	Chronic Spontaneous Urticaria (CSU)
Approval Length	6 months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand

XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment

AND

2 - Patient has experienced at least one of the following:

- Reduction in itching severity from baseline
- Reduction in the number of hives from baseline

Product Name: Xolair	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)

AND

2 - Patient is 18 years of age or older

AND

3 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [8, 9]

AND

4 - Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) [H]

AND

5 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Xolair	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NCS; 0-3 scale])

AND

2 - Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) [H]

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Xolair	
Diagnosis	IgE-Mediated Food Allergy

Approval Length	20 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of IgE Mediated Food Allergy as evidenced by one of the following:

- Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food
- Positive food specific IgE (greater than or equal to 6 kUA/L)
- Positive oral food challenge, defined as experiencing dose-limiting symptoms at a single dose of less than or equal to 300 mg of food protein

AND

1.1.2 Clinical history of IgE Mediated Food Allergy

OR

1.2 Provider attestation that patient has a history of severe allergic response, including anaphylaxis, following exposure to one or more foods

AND

2 - Patient is 1 year of age or older

AND

3 - Used in conjunction with food allergen avoidance

AND

4 - Both of the following:

- Baseline (pre-Xolair treatment) serum total IgE level is greater than or equal to 30 IU/mL and less than or equal to 1850 IU/mL
- Dosing is according to serum total IgE levels and body weight

AND

5 - Prescribed by or in consultation with one of the following:

- Allergist
- Immunologist

Product Name: Xolair	
Diagnosis	IgE-Mediated Food Allergy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic

XOLAIR	OMALIZUMAB FOR INJ 150 MG	44603060002120	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 75 MG/0.5ML	4460306000E510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML	4460306000E520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 75 MG/0.5ML	4460306000D510	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 150 MG/ML	4460306000D520	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN AUTO-INJECTOR 300 MG/2ML	4460306000D530	Brand
XOLAIR	OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML	4460306000E530	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy(e.g., reduction of type 1 allergic reactions, including anaphylaxis, following accidental exposure to one or more foods)

AND

2 - Used in conjunction with food allergen avoidance

AND

3 - Dosing will continue to be based on body weight and pretreatment total IgE serum levels

AND

4 - Prescribed by or in consultation with one of the following:

- Allergist
- Immunologist

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [3]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [5]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Beclometasone dipropionate (pMDI, extrafine particle, HFA)	50-100	> 100-200	> 200
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Budesonide (nebules)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle*, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50		n.a.
Fluticasone propionate (DPI)	50-100	> 100-200	> 200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	> 100-200	> 200
Mometasone furoate (pMDI, standard particle, HFA)	100		200

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. National treatment guidelines recommend the combination of an inhaled glucocorticosteroid and a long-acting beta2-agonist for the treatment of moderate persistent or severe persistent asthma. [2-5]
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. Clinical studies for allergic asthma evaluated an initial 16-week steroid stable phase in which subjects received omalizumab with a constant dose of inhaled steroids. This 16-week period may not be sufficient amount of time to show reduction in exacerbations. For allergic asthma, initial authorization duration increased from 16 weeks to 6 months. [3, 4]
C. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [3].
D. Sensitization to a perennial allergen (e.g., mite, cat, dog) should be required. [4] Xolair is indicated for children and adults (6 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. [1]
E. For chronic idiopathic urticaria, response observed at 12 weeks (one 24-week trial with data reported at 12 weeks, and one 12-week trial) [1]
F. Per clinical consult, April 2024.
G. Referral to an asthma specialist for consultation or comanagement is recommended if Xolair is being considered. [2]
H. Other agents used for nasal polyps include intranasal corticosteroids and nasal saline.

5 . References

1. Xolair Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2024.

2. National Heart, Lung, and Blood Institute, National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health Publication No.08-5846. Bethesda, MD, 2007. Available at: https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma. Accessed January 9, 2020.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023.
4. Per clinical consult with asthma specialist, January 6, 2011.
5. National Institute for Health and Care Excellence (NICE). Omalizumab for treating severe persistent allergic asthma (review of technology appraisal guidance 133 and 201). London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 64 p. (Technology appraisal guidance; no. 278). Available at https://www.nice.org.uk/guidance/ta278/resources/omalizumab-for-treating-severe-persistent-allergic-asthma-pdf-82600619176645. Accessed January 9, 2020.
6. Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014;133(5):1270-7.
7. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed March 11, 2021.
8. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immunol. 2014;113(4):347-85.
9. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. Int Forum Allergy Rhinol. 2016 Feb; Suppl 1:S22-209.
10. A, Boyce J, Ass'ad A, Burks Wesley, A et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. Journal of Allergy and Clinical Immunology. 2010; 126(6): 1079-1378.

6 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160994
Guideline Name	Xolremdi (mavorixafor)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xolremdi (mavorixafor)
WHIM syndrome Indicated in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.

2 . Criteria

Product Name: Xolremdi	
Diagnosis	WHIM syndrome
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLREMDI	MAVORIXAFOR CAP 100 MG	82502046000120	Brand

Approval Criteria

1 - Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome

AND

2 - Patient has genotype confirmed variant of CXCR4 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Patient has an absolute neutrophil count (ANC) less than 500 cells /µL [A]

AND

4 - Patient is 12 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Immunologist
- Hematologist
- Geneticist
- Allergist

Product Name: Xolremdi	
Diagnosis	WHIM syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XOLREMDI	MAVORIXAFOR CAP 100 MG	82502046000120	Brand

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in ANC, reduction in infections)

3 . Endnotes

A. Per consult with immunologist/ allergist, severe neutropenia (less than or equal to 500 cells per µL) is used in standard practice as a cut off for ANC levels [2].

4 . References

1. Xolremdi Prescribing Information. X4 Pharmaceuticals, Inc. Boston, MA. June 2024.
2. Per clinical consult with immunologist/ allergist, June 27, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160995
Guideline Name	Xtandi (enzalutamide)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Xtandi (enzalutamide)
Castration-resistant prostate cancer (CRPC) Indicated for the treatment of patients with castration-resistant prostate cancer (CRPC). **Metastatic castration-sensitive prostate cancer (mCSPC)** Indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). **Non-metastatic castration-sensitive prostate cancer (nmCSPC)** Indicated for the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR). **Off Label Uses: HRR Gene-mutated mCRPC [3]** Indicated for the treatment of adult patients with HRR gene-mutated metastatic castration-resistant prostate cancer (mCRPC) in combination with Talzenna (talazoparib).

2 . Criteria

Product Name: Xtandi	
Diagnosis	Castration-resistant prostate cancer (CRPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTANDI	ENZALUTAMIDE CAP 40 MG	21402430000120	Brand
XTANDI	ENZALUTAMIDE TAB 40 MG	21402430000320	Brand
XTANDI	ENZALUTAMIDE TAB 80 MG	21402430000340	Brand

Approval Criteria

1 - Diagnosis of castration-resistant (chemical or surgical) prostate cancer

AND

2 - If HRR gene-mutated metastatic disease, medication will be taken in combination with Talzenna (talazoparib)

Product Name: Xtandi	
Diagnosis	Metastatic castration-sensitive prostate cancer (mCSPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTANDI	ENZALUTAMIDE CAP 40 MG	21402430000120	Brand
XTANDI	ENZALUTAMIDE TAB 40 MG	21402430000320	Brand
XTANDI	ENZALUTAMIDE TAB 80 MG	21402430000340	Brand

Approval Criteria

1 - Diagnosis of metastatic, castration-sensitive prostate cancer

Product Name: Xtandi	
Diagnosis	Non-metastatic castration-sensitive prostate cancer (nmCSPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTANDI	ENZALUTAMIDE CAP 40 MG	21402430000120	Brand
XTANDI	ENZALUTAMIDE TAB 40 MG	21402430000320	Brand
XTANDI	ENZALUTAMIDE TAB 80 MG	21402430000340	Brand

Approval Criteria

1 - Diagnosis of non-metastatic, castration-sensitive prostate cancer (nmCSPC)

AND

2 - Patient has high-risk biochemical recurrence (BCR) defined by a PSA doubling time less than or equal to 9 months and one of the following:

- PSA values greater than or equal to 1 ng/mL if the patient had prior prostatectomy (with or without radiotherapy)
- PSA values at least 2 ng/mL above the nadir if the patient had prior radiotherapy only

Product Name: Xtandi	
Diagnosis	All indications listed above
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
XTANDI	ENZALUTAMIDE CAP 40 MG	21402430000120	Brand
XTANDI	ENZALUTAMIDE TAB 40 MG	21402430000320	Brand
XTANDI	ENZALUTAMIDE TAB 80 MG	21402430000340	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Xtandi prescribing information. Astellas Pharma Inc. Northbrook, IL. November 2023.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.3.2024. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed March 2024.
3. Agarwal, Neeraj, et al. “Talazoparib plus Enzalutamide in Men with First-Line Metastatic Castration-Resistant Prostate Cancer (TALAPRO-2): A Randomised, Placebo-Controlled, Phase 3 Trial.” The Lancet, 4 June 2023, https://doi.org/10.1016/s0140-6736(23)01055-3.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160996
Guideline Name	Yonsa (abiraterone acetate) - PA, NF
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Yonsa (abiraterone acetate)
Metastatic Castration-Resistant Prostate Cancer (mCRPC) Indicated in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer.

2 . Criteria

Product Name: Yonsa	
Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
YONSA	ABIRATERONE ACETATE MICRONIZED TAB 125 MG	21406010250310	Brand

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 For continuation of prior therapy

Product Name: Yonsa	
Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
YONSA	ABIRATERONE ACETATE MICRONIZED TAB 125 MG	21406010250310	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Yonsa	
Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
YONSA	ABIRATERONE ACETATE MICRONIZED TAB 125 MG	21406010250310	Brand

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

1. Yonsa prescribing information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. July 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed May 3, 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160997
Guideline Name	Zelboraf (vemurafenib)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zelboraf (vemurafenib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. Limitation of Use: ZELBORAF is not indicated for treatment of patients with wild-type BRAF melanoma. **Erdheim-Chester Disease** Indicated for the treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation.

2 . Criteria

Product Name: Zelboraf

Diagnosis	Melanoma
Approval Length	12 Month [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZELBORAF	VEMURAFENIB TAB 240 MG (BASE EQUIVALENT)	21532080000320	Brand
ZELBORAF	VEMURAFENIB TAB 240 MG	21532080000320	Brand

Approval Criteria

1 - One of the following diagnoses: [2]

- Unresectable melanoma
- Metastatic melanoma

AND

2 - Cancer is BRAF V600 mutant type as detected by an FDA-approved test (e.g., cobas 4600 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Zelboraf	
Diagnosis	Erdheim-Chester Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZELBORAF	VEMURAFENIB TAB 240 MG (BASE EQUIVALENT)	21532080000320	Brand
ZELBORAF	VEMURAFENIB TAB 240 MG	21532080000320	Brand

Approval Criteria

1 - Diagnosis of Erdheim-Chester disease (ECD)

AND

2 - Disease is BRAF V600 mutant type (MT)

Product Name: Zelboraf	
Diagnosis	All Indications
Approval Length	12 Month [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZELBORAF	VEMURAFENIB TAB 240 MG (BASE EQUIVALENT)	21532080000320	Brand
ZELBORAF	VEMURAFENIB TAB 240 MG	21532080000320	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

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 13, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160998
Guideline Name	Zepatier (elbasvir/grazoprevir)
Formulary	• Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) • Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zepatier (elbasvir/grazoprevir)
Chronic Hepatitis C (CHC) Indicated with or without ribavirin for the treatment of chronic hepatitis C virus (HCV) genotypes 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg.

2 . Criteria

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1a: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced WITHOUT baseline NS5A polymorphisms*

Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPATIER	ELBASVIR-GRAZOPREVIR TAB 50-100 MG	12359902300320	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1a

AND

2 - One of the following:

- Patient is 12 years of age or older
- Patient weight is at least 30 kg

AND

3 - One of the following:

3.1 Patient is treatment-naive

OR

3.2 Patient has prior failure to peginterferon alfa plus ribavirin treatment

OR

3.3 Both of the following:

- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)
- Used in combination with ribavirin

AND

4 - Both of the following: [1, A]

4.1 Patient has been tested for the presence of NS5A resistance-associated polymorphisms

AND

4.2 Patient is without baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

7 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Notes	*NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1a: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced WITH baseline NS5A polymorphisms*
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPATIER	ELBASVIR-GRAZOPREVIR TAB 50-100 MG	12359902300320	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1a

AND

2 - One of the following:

- Patient is 12 years of age or older
- Patient weight is at least 30 kg

AND

3 - One of the following:

- Patient is treatment-naive
- Patient has prior failure to peginterferon alfa plus ribavirin treatment
- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

4 - Both of the following: [1, A]

4.1 Patient has been tested for the presence of NS5A resistance-associated polymorphisms

AND

4.2 Patient has baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)

AND

5 - Used in combination with ribavirin

AND

6 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

7 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

8 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

9 - One of the following:

9.1 Both of the following:

9.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)

AND

9.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

9.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Notes	*NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1b: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPATIER	ELBASVIR-GRAZOPREVIR TAB 50-100 MG	12359902300320	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1b

AND

2 - One of the following:

- Patient is 12 years of age or older
- Patient weight is at least 30 kg

AND

3 - One of the following:

3.1 Patient is treatment-naive

OR

3.2 Patient has prior failure to peginterferon alfa plus ribavirin treatment

OR

3.3 Both of the following:

- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

6 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 4: Treatment-naive
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPATIER	ELBASVIR-GRAZOPREVIR TAB 50-100 MG	12359902300320	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 4

AND

2 - One of the following:

- Patient is 12 years of age or older
- Patient weight is at least 30 kg

AND

3 - Patient is treatment-naive

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

6 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 4: PegIFN/RBV-experienced
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZEPATIER	ELBASVIR-GRAZOPREVIR TAB 50-100 MG	12359902300320	Brand

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 4

AND

2 - One of the following:

- Patient is 12 years of age or older
- Patient weight is at least 30 kg

AND

3 - Patient has prior failure to peginterferon alfa plus ribavirin treatment

AND

4 - Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

7 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

3 . Endnotes

A. Testing patients with HCV genotype 1a infection for the presence of virus with NS5A resistance-associated polymorphisms is recommended prior to initiation of treatment with Zepatier to determine dosage regimen and duration. In subjects receiving Zepatier for 12 weeks, sustained virologic response (SVR12) rates were lower in genotype 1a-infected patients with one or more baseline NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93. [1]
B. Zepatier is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) due to the expected significantly increased grazoprevir plasma concentration and the increased risk of alanine aminotransferase (ALT) elevations. [1]

4 . References

Zepatier Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. December 2021.

American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 13, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-160999
Guideline Name	Zokinvy (lonafarnib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zokinvy (lonafarnib)
Hutchinson-Gilford Progeria Syndrome (HGPS) Indicated in patients 12 months of age and older with a body surface area (BSA) of 0.39 m^2 and above to reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS). Limitations of Use: ZOKINVY is not indicated for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies. Based upon its mechanism of action, ZOKINVY would not be expected to be effective in these populations. **Processing-Deficient Progeroid Laminopathies** Indicated in patients 12 months of age and older with a body surface area (BSA) of 0.39 m^2 and above for the treatment of processing-deficient Progeroid Laminopathies with either heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations. Limitations of Use: ZOKINVY is not indicated for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies. Based upon its mechanism of action, ZOKINVY would not be expected to be effective in these populations.

2 . Criteria

Product Name: Zokinvy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZOKINVY	LONAFARNIB CAP 50 MG	99463045000120	Brand
ZOKINVY	LONAFARNIB CAP 75 MG	99463045000130	Brand

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Hutchinson-Gilford Progeria Syndrome

OR

1.2 For treatment of processing-deficient Progeroid Laminopathies with one of the following:

Heterozygous LMNA mutation with progerin-like protein accumulation

Homozygous or compound heterozygous ZMPSTE24 mutations

AND

2 - Patient is 12 months of age or older

AND

3 - Patient has a body surface area of 0.39 m^2 and above

3 . References

Zokinvy Prescribing Information. Eiger BioPharmaceuticals, Inc. Palo Alto, CA. November 2020.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-161000
Guideline Name	Zolinza (vorinostat)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zolinza (vorinostat)
Cutaneous T-cell Lymphoma Indicated for treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies.

2 . Criteria

Product Name: Zolinza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZOLINZA	VORINOSTAT CAP 100 MG	21531575000120	Brand

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma

AND

2 - One of the following: [2]

2.1 Patient has progressive, persistent or recurrent disease on or following two systemic therapies (e.g., extracorporeal photopheresis [ECP], systemic retinoids, interferons) [A]

OR

2.2 History of contraindication or intolerance to other systemic therapies (e.g., Adcetris [brentuximab vedotin, Cytoxan [cyclophosphamide], Poteligeo [mogamulizumab]) [A]

Product Name: Zolinza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZOLINZA	VORINOSTAT CAP 100 MG	21531575000120	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

Examples of systemic therapies include (but are not limited to): [2] Adcetris (brentuximab vedotin), Cytoxan (cyclophosphamide), Doxil (pegylated doxorubicin), Extracorporeal photochemotherapy, Folotyn (pralatrexate), Gemzar (gemcitabine), Interferon-alpha, Leukeran (chlorambucil), Nipent (pentostatin), Poteligeo (mogamulizumab), Targretin (bexarotene), Temodar (temozolamide), Toposar (etoposide), Trexall (methotrexate), Velcade (bortezomib)

4 . References

Zolinza Prescribing Information. Merck & Co, Inc. Whitehouse Station, NJ. July 2022

National comprehensive cancer network (NCCN) clinical practice guidelines in oncology: Primary cutaneous lymphomas. v.2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed August 6, 2024.

5 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-161001
Guideline Name	Zydelig (idelalisib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zydelig (idelalisib)
Relapsed Chronic Lymphocytic Leukemia Indicated, in combination with rituximab, for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL) for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. Limitation of Use: Zydelig is not indicated and is not recommended for first-line treatment of any patient, including patients with CLL, small lymphocytic lymphoma (SLL), follicular lymphoma (FL), and other indolent non-Hodgkin lymphomas. Zydelig is not indicated and is not recommended in combination with bendamustine and rituximab, or in combination with rituximab for the treatment of patients with FL, SLL, and other indolent non-Hodgkin lymphomas.

2 . Criteria

Product Name: Zydelig	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYDELIG	IDELALISIB TAB 100 MG	21538040000320	Brand
ZYDELIG	IDELALISIB TAB 150 MG	21538040000330	Brand

Approval Criteria

1 - Diagnosis of Chronic Lymphocytic Leukemia (CLL)

AND

2 - Patient has relapsed on at least one prior therapy (e.g., purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab])

AND

3 - Used in combination with Rituxan (rituximab)* [2]

AND

4 - Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (e.g., coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD], etc.)

Notes	*This drug may require prior authorization.

Product Name: Zydelig	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYDELIG	IDELALISIB TAB 100 MG	21538040000320	Brand
ZYDELIG	IDELALISIB TAB 150 MG	21538040000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zydelig Prescribing Information. Gilead Sciences, Inc. Foster City, CA. February 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma. v.3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed August 2, 2022.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-161002
Guideline Name	Zykadia (ceritinib)
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zykadia (ceritinib)
Non-small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

2 . Criteria

Product Name: Zykadia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYKADIA	CERITINIB TAB 150 MG	21530514000330	Brand

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - One of the following: [2]

Disease is metastatic

Disease is recurrent

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - One of the following:

4.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

Alecensa (alectinib)

Alunbrig (brigatinib)

OR

4.2 For continuation of prior therapy

Product Name: Zykadia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYKADIA	CERITINIB TAB 150 MG	21530514000330	Brand

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zykadia Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2022.

The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 10, 2024.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24

Prior Authorization Guideline

Guideline ID	GL-161003
Guideline Name	Zytiga (abiraterone acetate) - PA, NF
Formulary	Quartz Commercial (QTZQHBPCC, QTZQHICC, QTZQHPMCC, QTZHPCC, QTZQHSS) Quartz EHB (QTZQHBPCA, QTZQHICA, QTZQHPCA, QTZQHPMCA)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Zytiga (abiraterone acetate)
Metastatic castration-resistant prostate cancer (mCRPC) Indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) in combination with prednisone. **Metastatic castration-sensitive prostate cancer (mCSPC)** Indicated for the treatment of patients with metastatic high risk castration-sensitive prostate cancer (mCSPC) in combination with prednisone.

2 . Criteria

Product Name: Brand Zytiga

Diagnosis	Castration-resistant prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYTIGA	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Brand
ZYTIGA	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Brand

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 For continuation of prior therapy

Product Name: Brand Zytiga	
Diagnosis	Castration-resistant prostate cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZYTIGA	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Brand
ZYTIGA	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Brand

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Generic abiraterone acetate	
Diagnosis	Castration-resistant prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Generic
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Generic

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

Product Name: Brand Zytiga	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYTIGA	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Brand
ZYTIGA	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Brand

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to one of the following:

Xtandi (enzalutamide)

Erleada (apalutamide)

OR

2.2 For continuation of prior therapy

Product Name: Brand Zytiga	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Product Name	Generic Name	GPI	Brand/Generic
ZYTIGA	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Brand
ZYTIGA	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Brand

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following:

Xtandi (enzalutamide)

Erleada (apalutamide)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Generic abiraterone acetate	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Generic
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Generic

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

Product Name: Brand Zytiga, Generic abiraterone acetate	
Diagnosis	Castration-sensitive prostate cancer, castration-resistant prostate cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Product Name	Generic Name	GPI	Brand/Generic
ZYTIGA	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Brand
ZYTIGA	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Brand
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 250 MG	21406010200320	Generic
ABIRATERONE ACETATE	ABIRATERONE ACETATE TAB 500 MG	21406010200330	Generic

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zytiga Prescribing Information. Janssen Biotech Inc. Horsham, PA. August 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer. v.4.2018. Available by subscription at: http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf. Accessed September 18, 2018.

4 . Revision History

Date	Notes
11/19/2024	Bulk Copy. CM 11.19.24