Keystone First CHIP

PRIOR AUTHORIZATION CRITERIA

Effective 10/13/2026

Title: Abaloparatide (Tymlos ™)/ teriparatide (Forteo®)

Applicable Drugs:

Brand Name	Generic Name
Tymlos™	abaloparatide
Forteo®	teriparatide

Policy:

Primary or hypogonadal osteoporosis in men and Glucocorticoid-induced osteoporosis in men or women

INITIAL CRITERIA: Teriparatide (Forteo®) is medically necessary when ALL of the following are met:

1. The member is 18 years of age or older; and
2. ONE of the following:
    a. Primary or hypogonadal osteoporosis in men; or
    b. Glucocorticoid-induced osteoporosis in men or women (daily dose greater than or equal to 2.5 mg prednisone or equivalent for at least 3 months); and
3. ONE of the following:
    a. Member is high risk for fracture defined by ONE of the following:
        1. History of osteoporotic fractures (low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm); or
        2. At least two risk factors for a fracture (e.g., endocrine disorders, gastrointestinal disorders, use of medications associated with low bone mass or bone loss such as corticosteroids); or
        3. Member has a T score of at least -2.5 standard deviations below the young adult mean (T-score ≤ -2.5); or
    b. Inadequate response or inability to tolerate ONE of the following osteoporosis therapies:
        1. Bisphosphonates; or
        2. Hormone replacement therapy; or
        3. Selective estrogen receptor modulators (SERMs); or
        4. Calcitonin salmon (Miacalcin); or
        5. Denosumab (Prolia); and
4. For Forteo® only, inadequate response or inability to tolerate Teriparatide® manufactured by Alvogen

Initial Authorization duration: 12 months

REAUTHORIZATION CRITERIA: Teriparatide (Forteo®) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response; and
2. ONE of the following:
    a. Cumulative lifetime therapy does not exceed 2 years; or
    b. For Forteo® only, member remains at or has returned to having a high risk for fracture despite a total of 24 months of use for parathyroid hormones

Reauthorization duration: 12 months

Postmenopausal osteoporosis

INITIAL CRITERIA: Abaloparatide (Tymlos™) or teriparatide (Forteo®) is medically necessary when ALL of the following are met:

1. The member is 18 years of age or older; and
2. Diagnosis of postmenopausal osteoporosis; and
3. ONE of the following:
    1. Member is high risk for fracture defined by ONE of the following:
        1. Member has a T score of at least -2.5 standard deviation below the young adult mean (T-score ≤ -2.5); or
        2. History of osteoporotic fractures (low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm); or
        3. At least two risk factors for a fracture (e.g., endocrine disorders, gastrointestinal disorders, use of medications associated with low bone mass or bone loss such as corticosteroids); or
    2. Inadequate response or inability to tolerate ONE of the following osteoporosis therapies:
        1. Bisphosphonates; or
        2. Hormone replacement therapy; or
        3. Selective-estrogen receptor modulators (SERMs); or
        4. Calcitonin-salmon (Miacalcin®); or
        5. Denosumab (Prolia®); and
4. For Forteo® only, inadequate response or inability to tolerate Teriparatide® manufactured by Alvogen

Initial Authorization duration: 12 months

REAUTHORIZATION CRITERIA: Abaloparatide (Tymlos™) or teriparatide (Forteo®) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response; and
2. ONE of the following:
    a. Cumulative lifetime therapy does not exceed 2 years; or
    b. For Forteo® only, member remains at or has returned to having a high risk for fracture despite a total of 24 months of use for parathyroid hormones

Reauthorization duration: 12 months

Increase bone density in men with osteoporosis at high risk for fracture

INITIAL CRITERIA: Abaloparatide (Tymlos®) is medically necessary when ALL of the following are met:

1. Diagnosis of primary or hypogonadal osteoporosis; and
2. The member is 18 years of age or older; and
3. Both of the following:
    a. 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
    b. One of the following:
        1. History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or
        2. Inadequate response or inability to tolerate at least one osteoporosis treatment (e.g., alendronate, zoledronic acid, Prolia [denosumab])

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Abaloparatide (Tymlos®) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response; and
2. Cumulative lifetime therapy does not exceed 2 years

Reauthorization duration: 12 months

* Coverage duration of Teriparatide and Tymlos™ is limited to 730-day supply max per lifetime. All other treatment durations are considered Experimental/Investigational.

**Osteoporosis defined as T score of the individual's bone mineral density (BMD) is at least -2.5 standard deviations below the young adult mean OR history of osteoporotic fracture (i.e. hip, spine, etc.)

P&T Approval Date: 11/2025

Title: Actinic Keratosis agents and Zyclara®

Applicable Drugs:

Brand Name	Generic Name
Solaraze® Klisyri™	diclofenac 3% Tirbanibulin
Zyclara™	Imiquimod

Policy:

INITIAL CRITERIA Diclofenac 3% (Solaraze®) gel, imiquimod (Zyclara®) 3.75%, 2.5%, or tirbanibulin (Klisyri®) is medically necessary when BOTH of the following are met:

1. Diagnosis of actinic keratosis; and
2. Member is 18 years of age or older; and
3. ONE of the following:
    a. For imiquimod (Zyclara®) 3.75%, 2.5% only, inadequate response or inability to tolerate imiquimod 5%; or
    b. For tirbanibulin (Klisyri®) only, inadequate response or inability to tolerate BOTH of the following generics:
        1. Fluorouracil; and
        2. Imiquimod

Initial authorization duration:

- 30 days for tirbanibulin (Klisyri®) and imiquimod (Zyclara®) 3.75%, 2.5%.
- 3 months for diclofenac 3% (Solaraze®)

REAUTHORIZATION CRITERIA Diclofenac 3% (Solaraze®) gel, imiquimod (Zyclara®) 3.75%, 2.5%, or tirbanibulin (Klisyri®) is medically necessary when there is documentation of a diagnosis of actinic keratosis at a different site.
Reauthorization duration:

- 30 days for tirbanibulin (Klisyri®) and imiquimod (Zyclara®) 3.75%, 2.5%.
- 3 months for diclofenac 3% (Solaraze®)

Genital warts

INITIAL CRITERIA Imiquimod (Zyclara®) 3.75% is medically necessary when BOTH of the following are met:

1. Diagnosis of genital warts; and
2. Member is 12 years of age or older; and
3. Inadequate response or inability to tolerate imiquimod 5%

Initial authorization duration: 30 days

REAUTHORIZATION CRITERIA Imiquimod (Zyclara®) 3.75% is medically necessary when there is documentation of positive clinical response to therapy.

P&T Approval Date: 11/2025

Title: Acute Seizure Activity Agents

Applicable Drugs:

Brand name	Generic name
Nayzilam®	Midazolam
Valtoco®	Diazepam

Policy:

INITIAL CRITERIA: Midazolam (Nayzilam®), or Diazepam (Valtoco®) nasal spray is approved when ALL of the following are met:

1. Diagnosis of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern; and

2. ONE of the following:
    1. For midazolam (Nayzilam®) only, member is 12 years of age or older; or
    2. For diazepam (Valtoco®) only, member is 6 years of age or older; and
3. Prescribed by or in consultation with a neurologist/epilepsy specialist

Initial Authorization duration: 2 years

REAUTHORIZATION CRITERIA: Midazolam (Nayzilam®) nasal spray, or diazepam (Valtoco®) nasal spray is reapproved when there is documentation of positive clinical response to therapy.
Reauthorization duration: 2 years

P&T Approval Date: 2/2026

Prior Authorization Group Description	**Adenosine Triphosphate-Citrate Lyase (ACL) inhibitors**
Drugs	Nexletol (bempedoic acid) Nexlizet (bempedoic acid/ezetimibe) Any newly marketed agent within the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by a cardiologist or specialist in the treatment of lipid disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved with a 3-month duration and reauthorization requests will be approved with a 12-month duration.
Other Criteria	**Initial Authorization:** All requests: • Member must have documentation of baseline low density lipoprotein cholesterol (LDL-C) • Member has tried and failed a high-intensity statin (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) at maximum tolerated dose for 3 months via claim history or chart notes OR documentation has been provided that the member is not able to tolerate a statin. • Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet". • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary medications appropriate for the requested use (per the references outlined in "Covered Uses" or has a medical reason why these drug(s) cannot be used (e.g., intolerance, contraindication). For medications where there is only one formulary agent, only that agent must have been ineffective or not tolerated. For Hyperlipidemia: • Member meets ONE of the following: o Member has a diagnosis of heterozygous familial hypercholesterolemia (FH) o Member has a diagnosis of primary hyperlipidemia • Member has tried and failed ezetimibe at a maximum tolerated dose and LDL-C is not at goal, or documentation has been provided that the patient is not able to tolerate ezetimibe. For Cardiovascular Risk Reduction: • Member has established cardiovascular disease (documented history of coronary artery disease, symptomatic peripheral arterial disease, and or cerebrovascular atherosclerotic disease) • Member does not have established cardiovascular disease but is considered high risk (one of the following): o Diabetes mellitus (type 1 or type 2) in females over 65 years of age or males over 60 years of age o A Reynolds Risk score > 30% or a SCORE Risk score > 7.5% over 10 years o A coronary artery calcium score >400 Agatston units at any time in the past. **Reauthorization:**

Revision/Review Date: 05/2026	• Documentation provided that the member has obtained clinical benefit from medication (e.g., LDL-C lowering from baseline) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Adjunctive treatment for Parkinson's Disease

Applicable Drugs:

Brand Name	Generic Name
Inbrija™	Levodopa inhalation
Nourianz™	Istradefylline
Apokyn®	Apomorphine

Policy:

Parkinson's Disease

INITIAL CRITERIA: Levodopa inhalation (Inbrija™), or istradefylline (Nourianz™) is approved when ALL of the following are met:

1. Diagnosis of Parkinson's disease and member is experiencing intermittent off episodes; and
2. Member is 18 years of age or older; and
3. Concurrent use of carbidopa/levodopa containing product at maximally tolerated dose; and
4. Prescribed by or in consultation with a neurologist; and
5. Member had inadequate response or inability to tolerate TWO of the following:
    a. MAO-B Inhibitor (e.g., rasagiline, selegiline); or
    b. Dopamine Agonist (e.g., pramipexole, ropinirole); or
    c. COMT inhibitor (e.g., entacapone)

Initial authorization duration: 2 years

REAUTHORIZATION CRITRIA: Levodopa inhalation (Inbrija®), or istradefylline (Nourianz™) is re-approved when ALL of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Concurrent use of carbidopa/levodopa containing product

Advanced Parkinson's Disease

INITIAL CRITERIA: Apomorphine (Apokyn®) is approved when ALL of the following are met:

1. Diagnosis of advanced Parkinson's disease and member is experiencing intermittent "off" episodes; and
2. Member is 18 years of age or older; and

3. One of the following:
    a. Member is receiving medication in combination with other medications for the treatment of Parkinson's disease at maximally tolerated dose (e.g., carbidopa/levodopa, pramipexole, ropinirole, etc…); or
    b. Member has a contraindication or intolerance to other medications for the treatment of Parkinson's disease; and
1. Member is not using the medication with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron); and
2. Prescribed by or in consultation with a neurologist

Initial authorization duration: 2 years

REAUTHORIZATION CRITRIA: Apomorphine (Apokyn®) is re-approved with documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Prior Authorization Group Description	**Adrenal Enzyme Inhibitors for Cushing's Syndrome**
Drugs	Recorlev (levoketoconazole), Isturisa (osilodrostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with a non-endogenous source of hypercortisolism, such as exogenous source of glucocorticoids or therapeutic use of ACTH. • Patient has a diagnosis of pituitary or adrenal carcinoma
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescribed by an endocrinologist or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For reauthorization, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 02/2026	**Initial Authorization:** • Member has a diagnosis of endogenous Cushing's syndrome. • Member is not a candidate for surgery, surgery is not an option, or prior surgery has not been curative. • Documented baseline urinary free cortisol (UFC) test ≥ 1.3 times ULN (within the past 30 days). • Medication is prescribed at an FDA approved dose. • For Isturisa, provider must also attest that baseline electrocardiogram (ECG) has been obtained and hypokalemia and/or hypomagnesemia has been corrected prior to initiating therapy if present • Member has had a documented trial and failure of one of the following: o ketoconazole o Metopirone (metyrapone) o Lysodren (mitotane) o cabergoline o Signifor/Signifor LAR (pasireotide) o etomidate OR • Member has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) as to why these medications cannot be used **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. decrease in urinary free cortisol from baseline.) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Agents for Homozygous Familial Hypercholesterolemia (HoFH)**
Drugs	Evkeeza (evinacumab-dgnb) Juxtapid (lomitapide) ****Please refer to the "Proprotein Convertase Subtilisin/kexin 9 (PCSK9) Inhibitors" policy for requests for medications in that class****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by cardiologist or specialist in treatment of lipid disorders.
Coverage Duration	If all of the above conditions are met, the initial request will be approved for up to a 6 month duration, and the reauthorization request will be approved for a 12 month duration.

Other Criteria	**Initial Authorization:**
	• Documentation of a diagnosis of homozygous familial hypercholesterolemia (HoFH) via either:
	  ○ Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9 or ARH adaptor protein gene locus; OR
	  ○ A clinical diagnosis of HoFH which includes: untreated LDL-C >500 mg/dL (>13 mmol/L) or treated LDL-C ≥300 mg/dL (>8 mmol/L), AND
	  ▪ Cutaneous or tendon xanthoma before age 10 years, OR
	  ▪ Elevated LDL-C levels consistent with heterozygous FH in both parents.
	• Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies.
	• If prescriber indicates member is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents.
	• Patient has tried and failed ezetimibe at a maximal tolerated dose or a medical reason was provided why the member is not able to use ezetimibe
	• Member has documented trial and failure with PCSK9 inhibitor for at least 3 months, or a medical reason has been provided, why member is unable to use a PCSK9 inhibitor indicated for HoFH to manage their condition.
	• Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet".
	• Documentation was provided of current LDL level
	
	Reauthorization:

Revision/Review Date 5/2026	• Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has achieved or maintained a LDL reduction from the levels immediately prior to initiation of treatment with Juxtapid or Evkeeza. • The patient's claim history shows consistent therapy (monthly fills). **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Agents for Primary Biliary Cholangitis**
Drugs	Iqirvo (elafibranor), Livdelzi (seladelpar)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restriction	Member must be 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist or gastroenterologist
Coverage Duration	If the criteria are met, the request will be approved for a 3 month duration for initial authorization and for up to a 12 month duration for reauthorization.
Other Criteria	**Initial Authorization:** • Diagnosis of primary biliary cholangitis (PBC) confirmed by at least two of the following criteria: a) Positive antimitochondrial antibody (AMA) test, or presence of other PBC-specific autoantibodies, including sp100 or gp210, if AMA test is negative b) Elevated serum alkaline phosphatase (ALP) level c) Histologic evidence of primary biliary cholangitis from a liver biopsy • Drug is being requested in addition to ursodeoxycholic acid (UDCA) due to patient having an inadequate response to UDCA monotherapy for at least 1 year, OR member has a documented medical reason (e.g., contraindication, intolerance, hypersensitivity) why UDCA cannot be used and is taking the requested drug as monotherapy • Prescriber attests the patient does not have complete biliary obstruction, decompensated cirrhosis (e.g., Child-Pugh Class B or C) • Submission of the following test results within 30 days of request: a) Serum ALP b) Total bilirubin **Reauthorization:** • Provider attests that the patient has not developed complete biliary obstruction, decompensated cirrhosis (e.g., Child-Pugh Class B or C) • Submission of lab tests confirming each of the following: o A decrease in ALP of ≥ 15% from baseline o ALP is less than 1.67 times the upper limit normal (ULN); defined as 118 U/L for females and 124 U/L for males o Total bilirubin ≤ ULN defined as 1.1 mg/dL for females and 1.5 mg/dL for males

Revision/Review Date 11/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Agents for Thrombocytopenia**
Drugs	Non-formulary: • Nplate (romiplostim) • Doptelet (avatrombopag) • Tavalisse (fostamatinib) • eltrombopag (Promacta) • Mulpleta (lusutrombopag) • Alvaiz (eltrombopag) • Wayrilz (rilzabrutinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a hematologist
Coverage Duration	• If the criteria are met, the request will be approved for 12 months for eltrombopag, Alvaiz, Nplate ,Tavalisse, and Wayrilz. • Doptelet will be approved for a maximum of 5 days for thrombocytopenia associated with chronic liver disease in adult patients requiring elective surgery and 12 months for immune thrombocytopenia (ITP) • Mulpleta will be approved for a maximum of 7 days.

Other Criteria	• **Chronic immune (idiopathic) thrombocytopenia (ITP):**
	  • Platelet level < 30,000 mm^3
	  • Documented trial and failure, intolerance or contraindication to use ONE of the following:
	  ▪ Glucocorticoids
	  ▪ Intravenous immune globulin (IVIG),
	  ▪ Rituximab
	  ▪ Splenectomy
	  • If the request is for Nplate, Doptelet, Alvaiz, Tavalisse, or Wayrilz, the member has a documented trial and failure, intolerance, or contraindication to eltrombopag
	• **Severe aplastic anemia** (eltrombopag and Alvaiz only):
	  • Documented trial and failure, intolerance or contraindication to use

	at least one immunosuppressive agent • Platelet level < 20,000 cells/microL OR platelet level < 30,000 cells/microL with bleeding OR reticulocyte level < 20,000 cells/microL OR absolute neutrophil level < 500 cells/microL • For Alvaiz, member must also have a documented trial and failure, intolerance, or contraindication to eltrombopag • **Thrombocytopenia in patients with Hepatitis C infection** (eltrombopag and Alvaiz only): • Diagnosis of chronic hepatitis C • Documentation of treatment with interferon-based therapy AND patient's degree of thrombocytopenia prevents the initiation or limits the ability to maintain interferon-based therapy • Medical reason for why patient needs to be treated with interferon over direct acting antiviral (DAA) medication • Platelet level < 50,000/mm^3 • For Alvaiz, member must also have a documented trial and failure, intolerance, or contraindication to eltrombopag • **Thrombocytopenia associated with chronic liver disease in *adult* patients requiring elective surgery** (Doptelet and Mulpleta only): • Patient has a diagnosis of chronic liver disease and is scheduled to undergo a procedure • Platelet level < 50,000/mm^3 • **For Mulpleta:** documentation of trial and failure, intolerance, or contraindication to use Doptelet
Revision/Review Date: 11/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Agents to Treat Gaucher Disease**
Drugs	Cerdelga (eliglustat tartrate), Cerezyme (imiglucerase), Vpriv (velaglucerase alfa), Elelyso (taliglucerase alfa), miglustat (Zavesca, Yargesa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist in treatment of Gaucher Disease (e.g. hematologist, orthopedist, endocrinologist, or geneticist).
Coverage Duration	If all of the criteria are met, the request will be approved for 6 months.
Other Criteria Revision/Review Date: 05/2026	**Initial Authorization:** • Request is for an FDA-approved dose Vpriv, Elelyso, or miglustat: • Member has a confirmed diagnosis of Gaucher disease, type 1 (GD1) Cerezyme: • Patient has a confirmed diagnosis of a non-central nervous system (CNS) manifestation of Gaucher disease, type 1 or type 3 Cerdelga: • Member has a confirmed diagnosis of Gaucher disease, type 1 • The member has been designated a Cytochrome P450 2D6 (CYP2D6) extensive metabolizer (EM), intermediate metabolizer (IM) or poor metabolizer (PM) as detected by an FDA-approved test. • Member is not concomitantly taking a Class IA (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic. • For EMs or IMs, member is not concomitantly taking a moderate or strong CYP2D6 inhibitor (e.g., fluoxetine, bupropion) WITH a moderate or strong Cytochrome P450 3A (CYP3A) inhibitor (fluconazole, ketoconazole). • For IMs and PMs, member is not concomitantly taking a strong CYP3A inhibitor • For EMs, patient does not have moderate or severe hepatic impairment • For IMs or PMs, patient does not have any degree of hepatic impairment • Patient has no pre-existing cardiac disease or long QT syndrome. **Re-Authorization criteria for all agents:** • Documentation has been provided that member has obtained clinical benefit from medication (e.g. increased platelet count, improvement in anemia, pulmonary function tests (PFTs), improvement in radiographic scans, improved quality of life) • Request is for an FDA-approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Alpelisib (Vijoice®)

Applicable Drugs:

Brand Name	Generic Name
Vijoice®	Alpelisib

Policy:

INITIAL CRITERIA Alpelisib (Vijoice) is medically necessary when ALL of the following are met:

1. Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS); and
2. Documentation of mutation in the PIK3CA gene; and
3. Member is 2 years of age or older; and
4. Documentation of severe clinical manifestations (e.g., Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal [CLOVES], Facial Infiltrating Lipomatosis [FIL], Klippel-Trenaunay Syndrome [KTS], Megalencephaly-Capillary Malformation Polymicrogyria [MCAP]); and
5. Prescribed by or in consultation with a provider who specialized in the treatment of PROS

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Alpelisib (Vijoice®) is medically necessary when ALL of the following are met:

1. Documentation of positive clinical response to therapy (e.g., radiological response defined as a ≥ 20% reduction from baseline in the sum of target lesion volume); and
2. Prescribed by or in consultation with a provider who specializes in the treatment of PROS

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Amifampridine**
Drugs	**Firdapse** (amifampridine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patients must be 6 years age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria Revision/Review Date 2/2026	**Initial Authorization:** • Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) based on at least one electrodiagnostic study (i.e., repetitive nerve stimulation, nerve conduction studies, electromyography) OR anti-P/Q-type voltage-gated calcium channel antibody testing • Member has been screened for small cell lung cancer (SCLC) and/or other malignancies • Member does not have a history of seizures • Medication is being prescribed at an FDA approved dose or is supported by compendia or standard of care guidelines **Re-authorization:** • Medication is prescribed at an FDA-approved dose or is supported by compendia or standard of care guidelines • Documentation provided that prescriber has evaluated the member and recommends continuation of therapy **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Amikacin liposome inhalation suspension (Arikayce)

Applicable Drugs:

Brand Name	Generic Name
Arikayce®	Amikacin liposome inhalation suspension

Policy:

INITIAL CRITERIA: Arikayce® (amikacin liposome inhalation suspension) is approved when ALL of the following are met:

1. Diagnosis of refractory Mycobacterium avium complex (MAC) lung disease; and
2. Member has not achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy; and
3. Documentation that the medication will be used as part of a combination antibacterial regimen; and
4. Member is 18 years of age or older; and
5. Prescribed by or in consultation with a pulmonologist or infectious diseases specialist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Arikayce® (amikacin liposome inhalation suspension) is re-approved when both of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Documentation that the medication will be used as part of a combination antibacterial regimen

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Authorization Group Description	**Androgenic Agents**
Drug(s)	*****If the request is for gender dysphoria for members under the age of 19, do not approve***** **<u>Formulary:</u>** Methyltestosterone oral capsule Testosterone (Axiron) 30 mg/actuation transdermal solution in metered pump Testosterone (Androgel 1%) transdermal gel packet Testosterone (Vogelxo, Testim) 1% (50 mg/ 5 g) transdermal gel packet, 12.5 mg/actuation pump Testosterone (Androgel 1.62%) transdermal gel packet, 20.25 mg/actuation pump, 40.5 mg/2.5 g transdermal gel Testosterone Cypionate Intramuscular Solution Testosterone Enanthate Intramuscular Solution **Non-Formulary:** Aveed (testosterone) 750 mg/3 ml (250 mg/ml) intramuscular solution Azmiro (testosterone cypionate) intramuscular syringe Jatenzo (testosterone undecanoate) capsules Kyzatrex (testosterone undecanoate) capsules Methitest (methyltestosterone) 10 mg tablet Natesto (testosterone) 5.5 mg/0.122 g/actuation nasal gel pump Testopel (testosterone) 75 mg implant pellet testosterone (Fortesta) 2% transdermal gel pump Tlando (testosterone undecanoate) capsules Undecatrex (testosterone undecanoate) capsules Xyosted (testosterone) subcutaneous auto-injector Any other marketed agent within the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert).
Exclusion Criteria	Men with carcinoma of the breast or known or suspected prostate cancer Pregnant or breastfeeding women Treatment of gender dysphoria for members under the age of 19
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria:	**<u>*Requests for treatment of gender dysphoria are excluded from benefit coverage for members under the age of 19*</u>** **<u>Initial Authorization</u>**: 1. Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired) 2. Documented low testosterone level(s) (<300 ng/dL for total testosterone; copy of laboratory result required) on two occasions with at least one level in the past 6 months 3. If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary medications appropriate for the requested use (per the references outlined in "Covered Uses" or has a medical reason why these drug(s) cannot be used (e.g., intolerance, contraindication). For medications where there is only one formulary agent, only that agent must have been ineffective or not tolerated.
Review/Revision Date: 10/2026	**<u>Re-Authorization:</u>** 1. Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). 2. Documentation that the member experienced a clinical benefit as a result of the medication. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Anzupgo (delgocitinib)**
Drugs	Anzupgo
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Current use of Opzelura (ruxolitinib), systemic JAK inhibitors, or potent immunosuppressants
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	None
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For reauthorization, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 11/2025	**<u>Initial Authorization:</u>** • Medication is prescribed at an FDA approved dose • Diagnosis of moderate to severe chronic hand eczema (CHE) • Documentation of hand eczema persisting for >3 months or recurring ≥2 times within 12-month time frame • Trial and failure, or contraindication to, ≥2 formulary moderate/high-potency topical corticosteroids **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (i.e. significant clearing of the skin, reduction in itching) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Antifibrotic Respiratory Tract Agents

Drugs:
Ofev (nintedanib esylate)
pirfenidone (Esbriet)

Covered Uses: Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.

INITIAL CRITERIA:

For all requests:

- Patient is 18 years of age or older
- Prescriber is a pulmonologist or lung transplant specialist
- Provider attests that they have reviewed the patient's other medications, and have addressed all potential drug interactions
- Documentation has been provided that the patient does not smoke

If the request is for Idiopathic Pulmonary Fibrosis (IPF):

- Confirmed diagnosis of IPF
- Pulmonary function test indicate patient has Forced Vital Capacity (%FVC) ≥ 50% within 30 days of request

If the request is for Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) *(Ofev only)*:

- Confirmed diagnosis of SSc-ILD
- FVC ≥ 40% within 30 days of request
- Trial and failure of mycophenolate mofetil (MMF), cyclophosphamide or azathioprine.

If the request is for Chronic Fibrosing Intersitial Lung Diseases (ILDs) with a progressive phenotype *(Ofev only)*:

- Diagnosis of chronic fibrosing ILD (such as connective tissue disease [CTD]-associated ILD, chronic fibrosing hypersensitivity pneumonitis [HP], idiopathic non-specific interstitial pneumonia [iNSIP], unclassifiable idiopathic interstitial pneumonia [IIP]) of a progressive phenotype
- Recent (12 month) history of treatment with at least one medication to treat ILD (e.g., corticosteroid, azathioprine, MMF, n-acetylcysteine (NAC), rituximab, cyclophosphamide, cyclosporine, or tacrolimus).
- FVC ≥ 45% predicted within 30 days of request

If all of the above conditions are met, the request will be approved for a 6 month duration; if all of the above criteria are not met, the request is referred to a Medical/clinical reviewer for medical necessity review.

REAUTHORIZATION CRITERIA:

- Prescriber is a pulmonologist or lung transplant specialist
- Documentation submitted indicates that the member has obtained clinical benefit from the medication
- Documentation has been provided that the patient does not smoke

If all of the above conditions are met, the request will be approved for a 6 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: 2/2026

Title: Aprocitentan (Tryvio™)

Applicable Drugs:

Brand Name	Generic Name
Tryvio™	Aprocitentan

Policy:

INITIAL CRITERIA: Aprocitentan (Tryvio™) is medically necessary when ALL of the following are met:

1. Diagnosis of treatment resistant hypertension; and
2. Member has not achieved target blood pressure (e.g., systolic blood pressure [SBP] less than 130 mmHg) after treatment with all of the following antihypertensive medications from different classes for an adequate duration (minimum 4 weeks each) at a maximally tolerated dose:
    1. One of the following:
        1. Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril); or
        2. Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan); and
    2. Diuretic (e.g., hydrochlorothiazide, chlorthalidone); and
    3. Calcium channel blocker (e.g., amlodipine, nifedipine); and
    4. Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]; and
3. Provider attests other causes of hypertension have been ruled out (e.g., secondary causes [primary hyperaldosteronism], white coat effect, medication nonadherence); and
4. Used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
5. Requested drug will be used in combination with at least 3 antihypertensive medications from different classes; and
6. Prescribed by or in consultation with a specialist experienced in the treatment of resistant hypertension (e.g., cardiologist, nephrologist)
7. Patient is not pregnant

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Aprocitentan (Tryvio™) is medically necessary when ALL of the following are met:

1. Member demonstrates positive clinical response to therapy (e.g., systolic blood pressure [SBP] less than 130 mmHg); and
2. Member continues to use Tryvio in combination with at least 3 antihypertensive medications from different classes and is adherent to therapy; and

3. Requested drug will continue to be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Prior Authorization Group Description	**Aqvesme**
Drugs	Aqvesme (mitapivat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the initial request will be approved for up to 6 months and reauthorization will be approved for up to 12 months.

Other Criteria
 	
Review/Revision Date: 05/2026
	Initial Authorization:
	• Documented diagnosis of one of the following forms of thalassemia confirmed by genetic testing:
	  o Beta thalassemia (with or without alpha-globin gene mutations)
	  o Hemoglobin E/beta thalassemia
	  o Alpha thalassemia/hemoglobin H disease
	• Documentation of one of the following:
	  o Hemoglobin ≤ 10 g/dL
	  o Member requires regular red blood cell (RBC) transfusions (defined as having had 6 to 20 RBC units transfused and no transfusion-free period of more than 6 weeks over the last 6 months)
	• Member does not have cirrhosis
	• Prescriber attests to measure liver laboratory tests (ALT, AST, ALP, and total bilirubin with fractionation) prior to initiation and during treatment
	• Member has not had prior exposure to gene therapy or prior bone marrow or stem cell transplantation
	• Medication is prescribed at an FDA approved dose
	
	Reauthorization:
	• Documentation of positive clinical benefit as evidenced by one of the following:
	  o Hemoglobin increase of at least 1 g/dL from baseline over a period of 12 weeks
	  o ≥50% reduction in transfused RBC units with a reduction of ≥ 2 units of transfused RBCs over a period of 12 weeks compared with baseline transfusion requirement
	• Member does not have cirrhosis or hepatocellular injury
	• Medication is prescribed at an FDA approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Title: Avacopan (Tavneos)

Applicable Drugs:

Brand Name	Generic Name
Tavneos™	Avacopan

Policy:

INITIAL CRITERIA: Avacopan (Tavneos™) is medically necessary when ALL of the following are met:

1. Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis:
    a. Granulomatosis with polyangiitis (GPA); or
    b. Microscopic polyangiitis (MPA); and
2. Member is receiving concurrent immunosuppressant therapy with one of the following:
    a. Cyclophosphamide; or
    b. Rituximab; and
3. One of the following:
    a. Member is concurrently on glucocorticoids (e.g., prednisone); or
    b. Inadequate response or inability to tolerate glucocorticoids (e.g., prednisone); and
4. Member is 18 years of age or older; and
5. Prescribed by or in consultation with one of the following:
    a. Nephrologist; or
    b. Pulmonologist; or
    c. Rheumatologist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Avacopan (Tavneos™) is medically necessary when ALL of the following are met:

1. Member does not show evidence of progressive disease while on therapy; and
2. Member is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab); and
3. Prescribed by or in consultation with one of the following:
    a. Nephrologist; or
    b. Pulmonologist; or
    c. Rheumatologist

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Aztreonam (Cayston)

Applicable Drugs:

Brand Name	Generic Name
Cayston®	Aztreonam

Policy:

INITIAL CRITERIA: Aztreonam (Cayston®) is approved when ALL of the following are met:

1. Member is 7 years of age or older; and
2. Diagnosis of cystic fibrosis; and
3. Evidence of Pseudomonas aeruginosa in the lungs confirmed by culture; and
4. Susceptibility results indicating that the Pseudomonas aeruginosa is sensitive to aztreonam; and
5. FEV1 that is 25% to 75% of predicted

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Aztreonam (Cayston®) is re-approved when ALL of the following are met:

1. Diagnosis of cystic fibrosis; and
2. Evidence of Pseudomonas aeruginosa in the lungs confirmed by culture; and
3. Documentation of positive clinical response to therapy (e.g. improvement in lung function demonstrated by improved FEV1)

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Becaplermin gel (Regranex®)

Applicable Drugs:

Brand name	Generic name
Regranex®	Becaplermin

Policy:

INITIAL CRITERIA: Becaplermin (Regranex®) gel is approved when ALL of the following are met:

1. Member 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)
3. Documentation of ulcer size

Initial authorization duration: 12 weeks

REAUTHORIZATION CRITERIA: Becaplermin (Regranex®) gel is re-approved when ONE of the following is met:

1. Documentation of lower extremity diabetic neuropathic ulcer at a different treatment site; or
2. Documentation ulcer size was reduced by 30% and there is continued need for treatment beyond 3 months

Reauthorization duration: 8 weeks

P&T Approval Date: 2/2026

Title: Belumosudil (Rezurock™)

Applicable Drugs:

Brand Name	Generic Name
RezurockTM	Belumosudil

Policy:

INITIAL CRITERIA Belumosudil (Rezurock™) is medically necessary when ALL of the following are met:

1. Diagnosis of chronic graft-versus-host disease; and
2. Member is 12 years of age or older; and
3. Inadequate response or inability to tolerate two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.); and
4. Prescribed by or in consultation with one of the following:
    a. Hematologist; or
    b. Oncologist; or
    c. Physician experienced in the management of transplant patients

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Belumosudil (Rezurock™) is medically necessary if member does not show evidence of progressive disease while on therapy
Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Benlysta (belimumab)**
Drugs	Benlysta (belimumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	Severe active central nervous system lupus
Required Medical Information	See "other criteria"
Age Restrictions	Must be at least 5 years of age
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	If all the criteria are met initial authorization requests may be approved for up to 6 months. Reauthorization requests may be approved for up to 12 months.
Other Criteria	**Initial Authorization**: • Active systemic lupus erythematosus (SLE) o Provider attestation that the patient is positive for autoantibodies (or antinuclear antibodies or anti–double-stranded DNA [anti-dsDNA] antibodies) o The member has tried and failed both of the following (or contraindication/inability to use these medications): ▪ Hydroxychloroquine ▪ One other immunosuppressant [e.g., methotrexate, azathioprine, calcineurin inhibitors or mycophenolate] • Active lupus nephritis o Provider attestation of diagnosis confirmed by kidney biopsy o The member has tried and failed, or has a medical reason for not using, both of the following ▪ Cyclophosphamide or tacrolimus ▪ Mycophenolate • Provider states the member will not be receiving concomitant therapy with the following: o B-cell targeted therapy including (but not limited to) rituximab o Interferon receptor antagonist, type 1 including (but not limited to) Saphnelo (anifrolumab) • Dosing is appropriate per labeling **Criteria for Reauthorization**: • Documentation or provider attestation of positive clinical response as indicated by one of the following: o Fewer flares that required steroid treatment o Lower average daily oral prednisone dose o Improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits o Sustained improvement in laboratory measures of lupus activity • Dosing is appropriate per labeling

Revision/Review Date: 5/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Benlysta (belimumab)**
Drugs	Benlysta (belimumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	Severe active central nervous system lupus
Required Medical Information	See "other criteria"
Age Restrictions	Must be at least 5 years of age
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	If all the criteria are met initial authorization requests may be approved for up to 6 months. Reauthorization requests may be approved for up to 12 months.
Other Criteria	**Initial Authorization**: • Active systemic lupus erythematosus (SLE) o Provider attestation that the patient is positive for autoantibodies (or antinuclear antibodies or anti–double-stranded DNA [anti-dsDNA] antibodies) o The member has tried and failed both of the following (or contraindication/inability to use these medications): ▪ Hydroxychloroquine ▪ One other immunosuppressant [e.g., methotrexate, azathioprine, calcineurin inhibitors or mycophenolate] • Active lupus nephritis o Provider attestation of diagnosis confirmed by kidney biopsy o The member has tried and failed, or has a medical reason for not using, both of the following ▪ Cyclophosphamide or tacrolimus ▪ Mycophenolate • Provider states the member will not be receiving concomitant therapy with the following: o B-cell targeted therapy including (but not limited to) rituximab o Interferon receptor antagonist, type 1 including (but not limited to) Saphnelo (anifrolumab) • Dosing is appropriate per labeling **Criteria for Reauthorization**: • Documentation or provider attestation of positive clinical response as indicated by one of the following: o Fewer flares that required steroid treatment o Lower average daily oral prednisone dose o Improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits

Revision/Review Date: 2/2026	○ Sustained improvement in laboratory measures of lupus activity • Dosing is appropriate per labeling **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Birch Triterpenes (Filsuvez)

Applicable Drugs:

Brand Name	Generic Name
Filsuvez®	Birch triterpenes

Policy:

INITIAL CRITERIA: Birch triterpenes (Filsuvez®) is medically necessary when ALL of the following are met:

1. Diagnosis of one of the following:
    1. Dystrophic epidermolysis bullosa (DEB); or
    2. Junctional epidermolysis bullosa (JEB); and
2. Disease is confirmed by one of the following:
    1. Genetic testing confirms mutation in one of the following genes:
        1. For Dystrophic epidermolysis bullosa (DEB), collagen type VII (COL7A1); or
        2. For Junctional epidermolysis bullosa (JEB), one of the following:
            1. ITGA6; or
            2. ITGB4; or
            3. Collagen type XVII (COL17A1); or
            4. LAMA3; or
            5. LAMB3; or
            6. LAMC2; or
            7. ITGA3; or
            8. LAMA3A; or
    2. Skin biopsy; and
3. Member is 6 months of age or older; and
4. Medication will be used for the treatment of wounds that require healing; and
5. DEB or JEB associated wounds are present for at least 21 days; and
6. Member does not have signs of infection for wound being treated; and
7. Member has no evidence or history of basal or squamous cell carcinoma for wound being treated; and
8. Member does not have history of stem cell transplant or gene therapy (e.g., Vyjuvek) for the treatment of epidermolysis bullosa; and
9. Standard wound care management not adequate in healing wounds (e.g., daily wound dressings, pain management, controlling infections); and
10. Prescribed by or in consultation with a dermatologist with expertise in the treatment of epidermolysis bullosa

Initial authorization duration: 3 months

REAUTHORIZATION CRITERIA: Birch triterpenes (Filsuvez®) is medically necessary when ALL of the following are met:

1. Member demonstrates positive clinical response to therapy as evidenced by wound is healing but not completely closed; and
2. Member does not have signs of infection for wound being treated; and
3. Member has no evidence or history of basal or squamous cell carcinoma for wound being treated; and
4. Prescribed by or in consultation with a dermatologist with expertise in the treatment of epidermolysis bullosa

Reauthorization duration: 6 months

P&T Approval Date: 2/2026

Field Name	Field Description
Prior Authorization Group Description	**Biologic Agents for Nasal Polyposis**
Drugs	**Dupixent** (dupilumab), **Xolair** (omalizumab), **Nucala** (mepolizumab), **Tezspire** (tezepelumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Use of Dupixent, Xolair, or Nucala concomitantly or with another pulmonary biologic (e.g. Fasenra, Cinqair)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an allergist or otolaryngologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	****Xolair: For asthma and urticaria, please refer to the "Xolair for Asthma, Urticaria, and IgE-Mediated Food Allergy" policy**** ****Dupixent: For atopic dermatitis, please refer to the "Agents for Atopic Dermatitis" policy; For asthma, please refer to the "Pulmonary Biologics for Respiratory and Eosinophilic Conditions" policy**** ****Nucala & Tezspire: For asthma or other eosinophilic conditions, please refer to the "Pulmonary Biologics for Respiratory and Eosinophilic Conditions" policy**** **<u>Initial Authorization:</u>**

	• Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)
	• Medication is being prescribed at an FDA approved dosage
	• Documentation of ONE of the following:
	  o Trial and failure, or medical reason for not using, all of the following therapies:
	  ▪ an intranasal corticosteroid
	  ▪ a systemic corticosteroid
	  o Prior surgery for nasal polyps
	• Patient is currently using an intranasal corticosteroid, will be prescribed at an intranasal corticosteroid, or has a documented medical reason for not using an intranasal corticosteroid
	
	<u>Re-authorization:</u>
	• Medication is prescribed at an FDA-approved dosage
	• Member will continue to use an intranasal corticosteroid, or has a medical reason for not using an intranasal corticosteroid
	• Documentation has been provided that demonstrates a clinical benefit (e.g. improvements in symptom severity, nasal polyp score [NPS], sino-nasal outcome test-22 [SNOT-22], nasal congestion score [NCS], nasal obstruction symptom visual analogue scale [VAS])

Revision/Review Date 2/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Brinsupri (brensocatib)**
Drugs	Brinsupri (brensocatib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 11/2025	**<u>Initial Authorization:</u>** • Diagnosis of bronchiectasis confirmed by chest CT scan • Documentation member does not have cystic fibrosis • At least 2 exacerbations in the past 12 months requiring an antibiotic prescription, urgent care or emergency room visit, or hospitalization • Medication is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (i.e. decrease in cough, sputum production, exacerbations, etc.) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Budesonide (Eohilia™)

Applicable Drugs:

Brand Name	Generic Name
Eohilia™	Budesonide oral suspension

Policy:
Budesonide (Eohilia™) is approved when ALL of the following are met:

1. Diagnosis of eosinophilic esophagitis (EoE); and
2. Member has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, heartburn, abdominal pain); and
3. Member has at least 15 intraepithelial eosinophils per high power field (HPF); and
4. Other causes of esophageal eosinophilia have been ruled out; and
5. Member is 11 years of age or older; and
6. Inadequate response or inability to tolerate a minimum 8-week duration of both of the following:
    1. Proton pump inhibitor (e.g., pantoprazole, omeprazole); and
    2. Topical (esophageal) corticosteroid (e.g., budesonide, fluticasone); and
7. Prescribed by or in consultation with one of the following:
    1. Allergist/immunologist; or
    2. Gastroenterologist

Authorization duration: 12 weeks

P&T Approval Date: 11/2025

Title: Carglumic acid (Carbaglu®)

Applicable Drugs:

Brand Name	Generic Name
Carbaglu®	Carglumic Acid

Policy:

Acute Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency

APPROVAL CRITERIA: Carglumic Acid (Carbaglu®) is medically necessary when all of the following are met:

1. Diagnosis of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; and
2. Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g., protein restriction, ammonia scavengers, dialysis)
3. Prescribed by or in consultation with a provider who specializes in the treatment of metabolic disorders

Authorization duration: 3 months

Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)

APPROVAL CRITERIA: Carglumic Acid (Carbaglu®) is medically necessary when all of the following are met:

1. Diagnosis of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA); and
2. Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g., intravenous glucose, insulin, protein restriction, dialysis); and
3. Patient's plasma ammonia level is greater than or equal to 50 micromol/L; and
4. Medication will be used for a maximum duration of 7 days; and
5. Prescribed by or in consultation with a provider who specializes in the treatment of metabolic disorders

Authorization duration: 3 months

Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency

INITIAL CRITERIA: Carglumic Acid (Carbaglu®) is medically necessary when all of the following are met:

1. Diagnosis of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; and
2. NAGS deficiency has been confirmed by genetic/mutational analysis; and

3. Medication will be used as maintenance therapy; and
4. Prescribed by or in consultation with a provider who specializes in the treatment of metabolic disorders

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Carglumic acid (Carbaglu®) is medically necessary when there is documentation of positive clinical response to therapy (e.g., plasma ammonia level within the normal range).

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Chelation Agents

Applicable Drugs:

Brand Name	Generic Name
Exjade	Deferasirox
Jadenu	Deferasirox
Ferriprox	Deferiprone

Policy:
Chronic iron overload in blood transfusions dependent anemia

INITIAL CRITERIA: Deferasirox (Exjade®/Jadenu®) is medically necessary when ALL of the following are met:

1. Diagnosis of chronic iron overload due to blood transfusions; and
2. Member is 2 years of age or older; and
3. Serum ferritin levels are consistently greater than 1000 mcg/L (as demonstrated with at least two lab values within two months prior to treatment)
4. For Brand Exjade and Brand Jadenu only, inadequate response or inability to tolerate generic deferasirox

Initial authorization duration: 12 months

CONTINUATION CRITERIA: Deferasirox (Exjade®/Jadenu®) is medically necessary there is documentation of a decreased serum ferritin level compared with baseline level for transfusion dependent anemia.

Continuation duration: 2 years

INITIAL CRITERIA: Deferiprone (Ferriprox®) is medically necessary when all of the following are met:

1. Diagnosis of transfusional iron overload due to Sickle Cell disease or other transfusion-dependent anemia; and
2. Member is 3 years of age or older; and
3. Inadequate response or inability to tolerate one of the following chelation therapy:
    a. Generic deferoxamine; or
    b. generic deferasirox; and
4. For Brand Ferriprox tablets only, Inadequate response or inability to tolerate generic deferiprone tablets; and
5. Current chelation therapy is inadequate

Initial authorization duration: 12 months

CONTINUATION CRITERIA: Deferiprone (Ferriprox®) is medically necessary when there is documentation of positive clinical response to therapy (e.g., decline in serum ferritin levels from baseline).

Continuation duration: 2 years

Chronic iron overload in non-transfusion-dependent Thalassemia Syndrome

INITIAL CRITERIA: Deferasirox (Exjade®/Jadenu®) is medically necessary when ALL of the following are met:

1. Diagnosis of chronic iron overload in Non-Transfusion-Dependent Thalassemia Syndromes; and
2. Member is 10 years of age or older; and
3. Serum ferritin levels are consistently greater than 300 mcg/L and liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) (as demonstrated with at least two lab values within 2 months prior to treatment)

Initial authorization duration: 12 months

CONTINUATION CRITERIA: Deferasirox (Exjade®/Jadenu®) is medically necessary when there is documentation of a decreased serum ferritin level compared with the baseline level or reduction in LIC (liver iron concentration) for non-transfusion dependent Thalassemia Syndrome

Continuation duration: 2 years

INITIAL CRITERIA: Deferiprone (Ferriprox®) is medically necessary when ALL of the following are met:

1. Diagnosis of transfusional iron overload due to Thalassemia Syndrome; and
2. Member is 3 years of age or older; and
3. Inadequate response or inability to tolerate one of the following chelation therapy:
    a. Generic deferoxamine; or
    b. Generic deferasirox; and
4. For Brand Ferriprox tablets only, Inadequate response or inability to tolerate generic deferiprone tablets; and
5. Current chelation therapy is inadequate

Initial authorization: 12 months

CONTINUATION CRITERIA: Deferiprone (Ferriprox®) is medically necessary when there is documentation of positive clinical response to therapy (e.g., greater than or equal to 20% decline in serum ferritin levels from baseline).
Continuation duration: 2 years

P&T Approval Date: 11/2025

Title: Cholic acid (Cholbam)

Applicable Drugs:

Brand Name	Generic Name
Cholbam®	cholic acid

Policy:

INITIAL CRITERIA Cholic acid (Cholbam®) is medically necessary when ALL of the following are met:

1. One of the following:
    a. Treatment of bile acid synthesis disorder due to a single enzyme defect (SED); or
    b. Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorder in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption; and
2. Prescribed by or in consultation with one of the following:
    a. hepatologist; or
    b. gastroenterologist; or
    c. medical geneticist; or
    d. other specialist that treats inborn errors of metabolism; and
3. No documentation of extrahepatic manifestations of bile acid synthesis disorders due to single enzyme defects (SEDs) or peroxisomal disorders (PDs) including Zellweger spectrum disorder

Initial authorization duration: 3 months

REAUTHORIZATION CRITERIA Cholic acid (Cholbam®) is medically necessary when there is documentation of improved liver function tests (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT]) from the start of treatment.

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Colchicine (Lodoco)

Applicable Drugs:

Brand Name	Generic Name
Lodoco	Colchicine

Policy:
INITIAL CRITERIA: Colchicine (Lodoco) is approved when all of the following are met:

1. Diagnosis of cardiovascular disease (CV); and
2. Used for the secondary prevention of CV disease (e.g., very high-risk patients); and
3. Member is 18 years of age or older; and
4. Member is on guideline therapy management for multiple risk factors (e.g., dyslipidemia, hypertension, hyperglycemia) associated with CV disease

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Colchicine (Lodoco) is re-approved when documentation is provided of positive clinical response to therapy

Reauthorization duration: 6 months

P&T Approval Date: 11/2025

Title: Complement Inhibitors Agents

Applicable Drugs:

Brand Name	Generic Name
Empaveli™	Pegcetacoplan
Voydeya™	Danicopan

Policy:

Paroxysmal Nocturnal Hemoglobinuria

INITIAL CRITERIA Pegcetacoplan (Empaveli™) is medically necessary when ALL of the following are met:

1. Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a hematologist/oncologist; and
4. Member's Hemoglobin (Hb) level is less than 10.5 g/dL

Initial authorization duration: 12 months

CONTINUATION CRITERIA Pegcetacoplan (Empaveli™) is medically necessary with documentation of positive clinical response to therapy (e.g., improvement in hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions)

Continuation authorization duration: 12 months

INITIAL CRITERIA: Iptacopan (Fabhalta®) is medically necessary when ALL of the following are met:

1. Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and
2. Member is 18 years of age or older; and
3. Member's Hemoglobin (Hb) level is less than 10 g/dL; and
4. Prescribed by or in consultation with a hematologist/oncologist

Initial authorization duration: 12 months

CONTINUATION CRITERIA: Iptacopan (Fabhalta®) is medically necessary with documentation of positive clinical response to therapy (e.g., improvement in hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions)

Continuation authorization duration: 12 months

INITIAL CRITERIA: Danicopan (Voydeya™) is medically necessary when ALL of the following are met:

1. Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and
2. Member is 18 years of age and older; and
3. Will be used as add-on therapy to ravulizumab (Ultomiris) or eculizumab (Soliris); and
4. Member's hemoglobin levels less than or equal to 9.5 g/dL; and
5. Absolute reticulocyte count greater than or equal to 120 x 109/L; and
6. Prescribed by or in consultation with a

hematologist/oncologist Initial authorization duration: 12

months

CONTINUATION CRITERIA: Danicopan (Voydeya™) is medically necessary when ALL of the following are met:

1. Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and
2. Documentation of positive clinical response to therapy (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions); and
3. Will be used as add-on therapy to ravulizumab (Ultomiris) or

eculizumab (Soliris) Continuation authorization duration: 12 months

P&T Approval Date: 02/2026

Title: Compounded products

Applicable Drugs:

Product	Description
Compound claims greater than $250	Compound where the submitted claim cost is greater than or equal to $250
Various	Compounding Kit

Policy:
A compounded product, including a commercially available compounding kit, is considered medically necessary when ALL of the following are met:

1. The active prescription ingredient(s) of the compound is FDA approved or supported by accepted compendium as stated in the Off-Label Use policy for the indication and route of administration; and
2. The product as compounded is not commercially available. This may include a current short supply* of the commercially available product or the member has a medical need for a dosage form, strength or formulation other than what can be accomplished with a commercially available product; and
3. Member had an inadequate response or inability to tolerate all commercially available therapeutic alternatives to treat the condition for which the compound has been requested; and
4. The compound does not contain any product(s) that were withdrawn or removed from the market due to safety reasons; and
5. The compound is not used for, nor does it contain, a product that is indicated for an excluded benefit (e.g., cosmetic)

Additionally, authorization may be placed to allow access to the prescription benefit for products that are not considered standard coverage (e.g. drugs administered intravenously) when all the following are met:

1. All of the above criteria are for medically necessary are met for the compounded product; and
2. The product is being used in a compound that will be administered through a route that is considered standard coverage for the prescription benefit (e.g., oral, topical, inhalation, etc.). Bladder installation may be considered if the above criteria are met.

Authorization length for short supply of the commercially available product will be six months. All other authorizations: 2 years

* http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

* http://www.ashp.org/Drug-Shortages/Current-Shortages

P&T Approval Date: 11/2025

Title: Continuous Glucose Monitor

Applicable Drugs:

Dexcom® line of products	Medtronic® line of products	Freestyle® line of products
Dexcom® G5 Receivers Dexcom® G6 Receivers Dexcom® G7 Receiver Dexcom® G5 Sensors Dexcom® G6 Sensors Dexcom® G7 Sensor Dexcom® G5 Transmitter Kit Dexcom® G6 Transmitter Kit	Guardian™ Connect Transmitter Guardian™ Sensor Enlite® Sensor Eversense® Sensor/Holder	Freestyle Libre® 14 Day Reader Freestyle Libre® 14 Day Sensor Freestyle Libre® 2 Reader Freestyle Libre® 2 Sensor Freestyle Libre® 3 Sensor

Policy:
INITIAL CRITERIA: Continuous glucose monitor (CGM) products (receivers, transmitters and sensors) are medically necessary when ALL of the following are met:

1. Diagnosis of diabetes; and
2. Member is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support; and
3. One of the following:
    1. Member is treated with insulin; or
    2. Member is non-insulin treated and experiences significant hypoglycemia (e.g., recurrent, unexplained, severe [generally blood glucose levels <50 mg/dL] hypoglycemia or hypoglycemic unawareness); and
4. For Freestyle Libre only, submission of documentation (e.g., chart notes) or paid claim history showing member had a minimum 90-day trial of Dexcom within the last 180 days

Initial authorization duration: 2 years.

REAUTHORIZATION CRITERIA: Continuous glucose monitor (CGM) products (receivers, transmitters and sensors) are medically necessary when ALL of the following are met:

1. Documentation that of a positive clinical response as evidenced by ONE of the following:
    1. Improvement in glycemic control (e.g., lower and/or maintain A1C levels); or
    2. Reduction or improvement in hypoglycemic events; and
2. For Freestyle Libre only, submission of documentation (e.g., chart notes) or paid claim history showing member had a minimum 90-day trial of Dexcom within the last 180 days

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Contraceptive Formulary Exception

Applicable Drugs:

N/A

Policy:
Non-formulary Exceptions:

Requests for treatment of gender dysphoria are excluded from benefit coverage for members under the age of 19

A non-formulary contraceptive is medically necessary for $0 cost-share when BOTH of the following are met:

1. The drug is described as a preventative medication identified by the Women's Preventive Services provision of the Patient Protection and Affordable Care Act (PPACA); and
2. The prescriber has provided documentation indicating the requested product is medically necessary

Authorization duration: 1 year

$0 Cost-Share Override

An exception to allow $0 cost-share for contraceptives covered on the formulary is medically necessary when BOTH of the following are met:

1. The drug is described as a preventative medication identified by the Women's Preventive Services provision of the Patient Protection and Affordable Care Act (PPACA); and
2. The prescriber has provided documentation indicating the requested product is medically necessary

Authorization duration: 1 year

*This policy does not apply to the Premium Formulary.

P&T Approval Date: 10/2026

Title: Convenience Packs

Applicable Drugs:

N/A

Policy:
Coverage is subject to the terms, conditions, and limitations of the member's contract.

Convenience packs as described above are not covered under the pharmacy benefit because each product is available independently.

A prescriber may issue a prescription or prescriptions for the individual components of the convenience pack. The individual components will be covered pursuant to the terms of member's benefit.

Examples of convenience packs include, but are not limited to:

- DermacinRx Clorhexacin, which contains the following:
  - Mupirocin 2% ointment – covered as a pharmacy benefit
  - Chlorhexidine gluconate 4% solution, dimethicone 5% cream not covered (not an FDA approved product)
- Diclovix DM PAK 1.5-8% which contains the following:
  - Diclofenac sodium solution 1.5% - covered as a pharmacy benefit
  - Menthol gel 8% therapy pack – not covered (not FDA approved product)

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Corticosteroids for Duchenne Muscular Dystrophy (DMD)**
Drugs	**Agamree (vamorolone)** **Deflazacort (Emflaza)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 2 years of age or older
Prescriber Restrictions	Prescribed by a neurologist, provider who specializes in the treatment of DMD, or in consultation with a neurologist of provider who specialized in the treatment of DMD
Coverage Duration	If all of the conditions are met, the initial request will be approved for a 6 month duration. For reauthorization, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 2/2026	**<u>Initial Authorization:</u>** • Confirmed diagnosis of Duchenne Muscular Dystrophy (such as documented mutation of dystrophin gene, genetic sequencing indicating mutations attributed to Duchene Muscular Dystrophy, muscle biopsy indicating absence of dystrophin protein, etc.), and copies of testing were submitted with request • Trial and failure with prednisone for at least 12 months, and documented medical reason why prednisone cannot be continued • The request is for an FDA approved dose **<u>Reauthorization:</u>** • Documentation or attestation of clinical benefit (such as improved muscle strength, muscle function, or overall symptom improvement) • The request is for an FDA approved dose **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Title: Cosmetic Policy

Applicable Drugs:

N/A

Policy:
Cosmetic drugs, or drugs prescribed for cosmetic purposes, are not covered under the pharmacy benefit. Cosmetic drugs or drugs prescribed for cosmetic purposes are:

- Used for other than the treatment of illness, injuries, congenital birth defect or restoration of physiological function; and
- Used for cleansing, beautifying, promoting attractiveness or altering the appearance of any part of the human body

Examples of drugs prescribed for cosmetic use include, but are not limited to:

Brand Name	Generic Name	FDA Indication
Egrifta SV	Tesamorelin	Reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.
Renova, Refissa (branded product only)	Tretinoin	Adjunctive agent for use in the mitigation (palliation) of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin in patients who do not achieve such palliation using comprehensive skin care and sun avoidance programs alone
Propecia 1mg	Finasteride 1mg	Male pattern alopecia
Multiple (e.g., Blanche cream 4%)	Hydroquinone	Discoloration of skin; Hyperpigmentation of skin
Latisse 0.03% solution	Bimatoprost	Hypotrichosis of the eyelashes
Vaniqa 13.9% cream	Eflornithine	Reduction of unwanted facial hair in women
Multiple (e.g., Rogaine)	Minoxidil topical	Male pattern alopecia; hair regrowth in women

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Crenessity**
Drugs	Crenessity (crinecerfont)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with non-classic congenital adrenal hyperplasia (CAH) • Patients with adrenal insufficiency due to causes other than 21-hydroxylase deficiency
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or other specialist experienced in managing congenital adrenal hyperplasia
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 05/2026	**Initial Authorization:** • Medically confirmed diagnosis of classic 21-hydroxylase deficiency congenital adrenal hyperplasia (CAH) • Patient is currently on stable regimen of glucocorticoid therapy and will continue to use glucocorticoids in combination with Crenessity • Medication is prescribed at an FDA approved dose according to package insert (patient's current weight must be provided) • For all adults and pediatric patients weighing ≥55 kg or patients weighing ≥20 kg if CYP3A4 dose adjustment is required: capsule formulation is requested, or documentation is provided that patient is unable to swallow capsule whole • Dosing requests for capsule formulations will employ strategies to minimize the total number of capsules used daily (i.e. "doubling up" on lower strength capsules to achieve a higher dose when the requested dose strength exists will not be authorized). **Re-Authorization:** • Documentation is provided that patient has successfully achieved a reduction in glucocorticoid dosage from baseline. • Medication is prescribed at an FDA approved dose according to package insert (patient's current weight must be provided) • For all adults and pediatric patients weighing ≥55 kg or patients weighing ≥20 kg if CYP3A4 dose adjustment is required: capsule formulation is requested, or documentation is provided that patient is unable to swallow capsule whole • Dosing requests for capsule formulations will employ strategies to minimize the total number of capsules used daily (i.e. "doubling up" on lower strength capsules to achieve a higher dose when the requested dose strength exists will not be authorized). **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Cyanocobalamin inhalation (Nascobal®)

Applicable Drugs:

Brand Name	Generic Name
Nascobal	Cyanocobalamin

Policy:
INITIAL CRITERIA Cyanocobalamin inhalation (Nascobal®) is medically necessary when ALL of the following are met:

1. Diagnosis of ONE of the following:
    a. Pernicious anemia in members requiring maintenance therapy who are in remission following intramuscular vitamin B12 therapy and who have no nervous system involvement; or
    b. Dietary deficiency of vitamin B12 due to strict vegetarian diet; or
    c. Malabsorption of vitamin B12 due to a structural or functional damage to the stomach or ileum; or
    d. Inadequate secretion of intrinsic factor; or
    e. Competition for vitamin B12 by intestinal parasites or bacteria (e.g., tapeworm, blind loop syndrome); or
    f. Inadequate utilization of vitamin B12 (e.g., antimetabolites are employed in treatment of neoplasia); and
2. Member is 18 years of age or older; and
3. Inadequate response or inability to tolerate oral and sublingual cyanocobalamin or member has a documented diagnosis of trypanophobia (i.e., needle-phobia)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Cyanocobalamin inhalation (Nascobal®) is medically necessary when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Cyclosporine (Verkazia®)

Applicable Drugs:

Brand Name	Generic Name
Verkazia®	Cyclosporine ophthalmic emulsion

Policy:
INITIAL CRITERIA Cyclosporine (Verkazia®) is approved when ALL of the following are met:

1. Diagnosis of moderate to severe vernal keratoconjunctivitis confirmed by the presence of clinical signs and symptoms (e.g., itching, photophobia, giant papillae at the upper tarsal conjunctiva or at the limbus, thick mucus discharge, conjunctival hyperaemia); and
2. Member is 4 years of age or older; and
3. Inadequate response or inability to tolerate one of the following:
    a. Topical ophthalmic "dual-acting" mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine); or
    b. Topical ophthalmic mast cell stabilizers (e.g., cromolyn); and
4. Inadequate response or inability to tolerate short term use (up to 2 to 3 weeks), of topical ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluoromethalone); and
5. Prescribed by or in consultation with one of the following:
    a. Ophthalmologist or
    b. Optometrist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Cyclosporine (Verkazia®) is re-approved when there is documentation of positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms (e.g., itching, photophobia, papillary hypertrophy, mucus discharge, conjunctival hyperaemia).

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Cysteamine-containing products

Applicable Drugs:

Brand Name	Generic Name
Cystagon®	Cysteamine Bitartrate
Cystaran®/Cystadrops®	Cysteamine Hydrochloride
Procysbi®	Cysteamine Bitartrate

Policy:

Cystinosis

INITIAL CRITERIA: Cysteamine hydrochloride (Cystaran®/Cystadrops®) Ophthalmic Solution is medically necessary when ALL of the following are met:

1. Diagnosis of cystinosis; and
2. Member has corneal cystine crystal accumulation; and
3. Prescribed by or in consultation with an ophthalmologist or a specialist with experience in treating cystinosis with corneal cystine crystal accumulation

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Cysteamine hydrochloride (Cystaran®, Cystadrops®) is medically necessary when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

Nephrotic Cystinosis

INITIAL CRITERIA: Cysteamine bitartrate (Cystagon®) is medically necessary when there is a diagnosis of nephrotic cystinosis.

Initial authorization: 2 years

REAUTHORIZATION CRITERIA Cysteamine bitartrate (Cystagon®) is medically necessary when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

INITIAL CRITERIA: Cysteamine bitartrate (Procysbi®) is medically necessary when ALL of the following are met:

1. Diagnosis of nephrotic cystinosis; and
2. Member is 1 year of age or older; and

3. Inadequate response or titration from cysteamine bitartrate immediate release capsules (Cystagon®)

Initial Authorization duration: 2 years

REAUTHORIZATION CRITERIA: Cysteamine bitartrate (Procysbi®) is medically necessary when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Prior Authorization Group Description	**Cystic Fibrosis transmembrane conductance regulator (CFTR) Modulators**
Drug(s)	Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) Kalydeco, Kalydeco Granules (ivacaftor) Orkambi, Orkambi Granules (lumacaftor/ivacaftor) Symdeko (tezacaftor/ivacaftor) Trikafta (elexacaftor/tezacaftor/ivacaftor) any newly marketed CFTR modulator to treat cystic fibrosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescribed by a pulmonologist or specialist in the treatment of cystic fibrosis
Coverage Duration	If all of the criteria are met the initial request will be 6 months. Reauthorization requests will be 12 months.
Other Criteria Review/Revision Date 2/2026	<u>Initial criteria:</u> • Documentation provided includes a copy of the FDA-cleared cystic fibrosis (CF) mutation test OR documentation from the National Cystic Fibrosis Registry (e.g., screen shot) with member's genetic mutations • The request is for an FDA approved indication for the member's genotype and within dosing guidelines • The request is appropriate for member (e.g., age/weight) based on FDA-approved package labeling, peer reviewed medical literature and nationally-recognized compendia. <u>Reauthorization:</u> • Based on prescriber's assessment, member continues to benefit from therapy • The request is within FDA dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Dalfampridine**
Drugs	dalfampridine (Ampyra) tablets
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• History of seizures Moderate or severe renal impairment (creatinine clearance ≤ 50mL/minute)
Required Medical Information	See "other criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If all of the conditions are met, the initial request will be approved for 6 month duration. Requests for reauthorization will be approve for 12 months.
Other Criteria	**Initial Authorization:** • Baseline creatinine clearance (within 60 days of request) • Patient has diagnosis of multiple sclerosis (MS) • Patient is ambulatory AND has a walking impairment • Baseline 25 foot walk was submitted with request • Documentation was submitted (consistent with pharmacy claims data, OR for new members to the health plan, consistent with chart notes) that patient is currently being treated with a disease modifying therapy (DMT) for MS (e.g. immunomodulator, interferon, immunosuppressive), or documentation of a medical reason (intolerance, hypersensitivity) as to why patient is unable to use one of these agents to treat their medical condition • Drug is being requested at an FDA approved dose **Re-authorization:** • Prescriber attests patient's walking has improved with dalfampridine therapy • Documentation was submitted patient is on a DMT for MS (e.g. immunomodulator, interferon, immunosuppressive), or documentation of a medical reason (intolerance, hypersensitivity) as to why patient is unable to use one of these agents to treat their medical condition • Drug is being requested at an FDA approved dose
Revision/Review Date 2/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Dextromethorphan hydrobromide and quinidine sulfate (Nuedexta)

Applicable Drugs:

Brand Name	Generic Name
Nuedexta®	dextromethorphan hydrobromide and Quinidine sulfate

Policy:
INITIAL CRITERIA: Dextromethorphan hydrobromide and quinidine sulfate (Nuedexta®) is medically necessary when ALL of the following are met:

1. Diagnosis of pseudobulbar affect; and
2. Prescribed by or in consultation with a neurologist or psychiatrist; and
3. Member is 18 years of age or older; and
4. There is an absence of cardiac rhythm disorder documented by a cardiac test (e.g., electrocardiogram); and
5. Member has one of the following conditions:
    a. Amyotrophic lateral sclerosis
    b. Multiple sclerosis
    c. Alzheimer's disease
    d. Parkinson's disease
    e. Stroke
    f. Traumatic brain injury

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Dextromethorphan hydrobromide and quinidine sulfate (Nuedexta®) is medically necessary when both of the following are met:

1. Documentation of clinical benefit from ongoing therapy (e.g., decrease in laughing/crying episodes); and
2. Prescribed by or in consultation with a neurologist or psychiatrist

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Dichlorphenamide (Keveyis®, Ormalvi®)

Applicable Drugs:

Brand Name	Generic Name
Keveyis®, Ormalvi®	Dichlorphenamide

Policy:
INITIAL CRITERIA: Dichlorphenamide (Keveyis®, Ormalvi®) is approved when of ALL of the following are met:

1. Treatment of primary hyperkalemic periodic paralysis, primary hypokalemic paralysis, and related variants; and
2. Prescribed by or in consultation with a neurologist; and
3. No documentation of ANY of the following:
    a. Concomitant use of high dose aspirin; or
    b. Severe pulmonary disease; or
    c. Hepatic insufficiency; and
4. Member is 18 years of age or older; and
5. One of the following:
    a. Member has positive genetic panel for periodic paralysis; or
    b. One of the following tests demonstrated positive results for periodic paralysis:
        1. EMG/nerve conduction studies, or
        2. Long exercise test, or
        3. Muscle biopsy, or
        4. Muscle MRI

Initial authorization duration: 3 months

CONTINUAITON CRITERIA: Dichlorphenamide (Keveyis®, Ormalvi®) is reapproved when there is documentation of positive clinical response to therapy as evidenced by a decrease in weekly attack frequency from baseline .

Continuation authorization duration: 2 years

P&T Approval Date: 11/2025

Title: Diclofenac Products

Applicable Drugs:

Brand Name	Generic Name
Flector®/Licart® Patch	Diclofenac epolamine 1.3% patch
Pennsaid® Solution	Diclofenac sodium 1.5%, 2% solution

Policy:
INITIAL CRITERIA: diclofenac epolamine (Flector®/Licart®) patch, diclofenac sodium 2% solution or Pennsaid® is approved when BOTH of the following are met:

1. Diagnosis of pain; and
2. ONE of the following:
    1. BOTH of the following:
        1. Inadequate response or inability to tolerate TWO of the following:
            1. Meloxicam
            2. Celecoxib
            3. Other oral NSAID; and
        2. Inadequate response or inability to tolerate ONE of the following:
            1. Generic topical diclofenac gel 1%
            2. Generic topical diclofenac solution 1.5%; or
3. BOTH of the following:
    1. Member is 65 years of age or older; and
    2. Inadequate response or inability to tolerate ONE of the following:
        1. Generic topical diclofenac gel 1%
        2. Generic topical diclofenac solution 1.5%

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: diclofenac epolamine (Flector®/Licart®) patch, diclofenac sodium 2% solution or Pennsaid® is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

P&T Approval Date: 2/2026

Title: Doxycycline, Minocycline ER/IR (Oracea, Emrosi)

Applicable Drugs:

Brand Name	Generic Name
Oracea	doxycycline IR/ER
Emrosi	minocycline hydrochloride

Policy:

INITIAL CRITERIA: Doxycycline IR/ER (Oracea), minocycline IR/ER (Emrosi™) is medically necessary when ALL of the following are met:

1. Diagnosis of inflammatory lesions (papules and pustules) rosacea; and
2. Member is 18 years of age or older; and
3. Inadequate response or inability to tolerate both generic doxycycline IR 20mg tablets and minocycline

Initial authorization duration: 9 months

REAUTHORIZATION CRITERIA: Doxycycline IR/ER (Oracea), minocycline IR/ER (Emrosi™) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Documentation of continued need for treatment beyond 9 months

Reauthorization duration: 2 years

P&T Approval Date: 2/2026

Title: Doxylamine/pyridoxine (Diclegis, Bonjesta)

Applicable Drugs:

Brand name	Generic name
Diclegis	doxylamine/ pyridoxine
Bonjesta	doxylamine/ pyridoxine

Policy:
Doxylamine/pyridoxine (Diclegis®, Bonjesta®) is medically necessary when ALL of the following are met:

1. Diagnosis of nausea and vomiting of pregnancy; and
2. Inadequate response to conservative management (e.g., change in dietary habits, ginger, acupressure, etc.); and
3. Inadequate response or inability to tolerate generic doxylamine and generic pyridoxine (Vitamin B6) taken together.

Authorization duration: 9 months

P&T Approval Date: 11/2025

Title: Droxidopa (Northera®)

Applicable Drugs:

Generic	Brand
Droxidopa	Northera®

Policy:
INITIAL CRITERIA: Droxidopa (Northera®) is approved when ALL of the following are met:

1. Diagnosis of symptomatic neurogenic orthostatic hypotension; and
2. Prescribed by, or in consultation with, ONE of the following:
    a. Cardiologist; or
    b. Neurologist; or
    c. Nephrologist; and
3. Member is 18 years of age or older; and
4. Attempt has been made to manage neurogenic orthostatic hypotension through at least one non-pharmacologic intervention (e.g. use of compression stockings/abdominal binder, increasing salt/fluid intake, participation in regular exercise, discontinue or reduce hypotensive or antihypertensive medications); and
5. Inadequate response or inability to tolerate midodrine or fludrocortisone; and
6. For the Brand Northera only, inadequate response or inability to tolerate generic droxidopa

Initial authorization duration: 1 month

REAUTHORIZATION CRITERIA: Droxidopa (Northera®) is re-approved when ALL of the following are met:

1. Diagnosis of symptomatic neurogenic orthostatic hypotension; and
2. For the Brand Northera only, inadequate response or inability to tolerate generic droxidopa; and
3. Prescribed by, or in consultation with, ONE of the following:
    1. Cardiologist; or
    2. Neurologist; or
    3. Nephrologist; and
4. Documentation of positive clinical response to therapy (e.g. improvement in symptoms such as orthostatic dizziness, lightheadedness, etc.)

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Title: Drugs Exceeding Claim Dollar Limit Threshold

Applicable Drugs:

Drug claims where total drug cost exceeds $10,000

Policy:
Claims that exceed $10,000 are approved when the use, including indication, dose, frequency, quantity, and duration, for the requested drug is approved by the FDA or considered medically accepted per Off-Label Use policy.

Authorization duration: 2 years, or for the duration of applicable medical necessity approval (for submitted cost plus $3000)

P&T Approval Date: 11/2025

Title: Dupilumab (Dupixent)

Applicable Drugs:

Brand Name	Generic Name
Dupixent®	dupilumab

Policy:

Atopic Dermatitis

INITIAL CRITERIA: Dupilumab (Dupixent®) is medically necessary ALL of the following are met:

1. Member is 6 months of age or older; and
2. Diagnosis of moderate-severe atopic dermatitis; and
3. One of the following:
    1. Involvement of at least 10% body surface area (BSA)
    2. SCORing Atopic Dermatitis (SCORAD) index value of at least 25; and
4. Prescribed by or in consultation with a dermatologist, allergist, or immunologist; and
5. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following:
    1. Topical steroids, medium potency or higher; or
    2. Topical tacrolimus; or
    3. Topical pimecrolimus; or
    4. Eucrisa; or
    5. Opzelura; and
6. No concurrent therapy with any other biologic agents; and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Documentation of positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity); and
2. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Moderate to severe asthma

INITIAL CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Member is 6 years of age or older; and
2. One of the following:
    1. Submission of documentation (e.g., chart notes) confirming a diagnosis of moderate to severe asthma with an eosinophilic phenotype defined as blood eosinophil levels of at least 150 cells/mcL at baseline or at least 300 cells/mcL within the past 12 months; or
    2. Submission of documentation (e.g., chart notes) confirming a diagnosis of Moderate to severe oral corticosteroid-dependent asthma; and
3. ONE of the following:
    1. Member is 6 to less than 12 years of age and paid claim or submission of documentation (e.g., chart notes) confirming the member is currently being treated or has a contraindication or intolerance to one of the following:
        1. Medium-dose inhaled corticosteroids (e.g., greater than 100-200mcg fluticasone propionate equivalent/day) and ONE additional 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
        2. One medium-dose combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Bre Ellipta [fluticasone furoate/vilanterol], Symbicort® [budesonide/formoterol]); or
    2. Member is 12 years of age or older and paid claims or submission of documentation (e.g., chart notes) confirming member is currently being treated or has a contraindication or intolerance to one of the following:

        1. High dose inhaled corticosteroid (e.g., greater than or equal to 500mcg fluticasone propionate equivalent/day); and ONE additional 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

2. One maximally dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Bre Ellipta [fluticasone furoate/vilanterol], Symbicort [budesonide/formoterol]); and

4. One of the following:
    1. Member has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months; or
    2. Prior asthma-related hospitalization within the past 12 months; and
5. Prescribed by or in consultation with a pulmonologist or allergy/ immunology specialist; and
6. No concurrent therapy with any other biologic agents; and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

CONTINUATION CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, decreased use of rescue medications); and
2. ONE of the following:
    1. Member is 6 to less than 12 years of age and paid claim or submission of documentation (e.g., chart notes) confirming the member is current being treated or has a contraindication or intolerance to one of the following:
        1. Medium-dose inhaled corticosteroids (e.g., greater than 100-200mcg fluticasone propionate equivalent/day) with or without ONE additional 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
        2. One medium-dose combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Bre Ellipta [fluticasone furoate/vilanterol], Symbicort® [budesonide/formoterol]); or
    2. Member is 12 years of age or older and paid claims or submission of documentation (e.g., chart notes) confirming member is currently being treated or has a contraindication or intolerance to one of the following
        1. High dose inhaled corticosteroid (ICS) (e.g., greater than or equal to 500mcg fluticasone propionate equivalent/day); with or without ONE additional 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
        2. One maximally dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Bre Ellipta [fluticasone furoate/vilanterol], Symbicort [budesonide/formoterol]); and
3. Prescribed by or in consultation with a pulmonologist or allergy/immunology specialist; and
4. No concurrent therapy with any other biologic agents; and
5. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Continuation authorization duration: 12 months

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

INITIAL CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Submission of documentation (e.g., chart notes) confirming diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); and
2. Member is 12 years of age or older; and
3. Prescribed by or in consultation with an allergist, immunologist, or Ear Nose Throat specialist; and
4. Paid claims or submission of documentation (e.g., chart notes) confirming an inadequate response or inability to tolerate at least a 2-month treatment with intranasal corticosteroid (e.g., fluticasone); and
5. Used in combination with another agent for CRSwNP; and
6. No concurrent therapy with any other biologic agents; and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial Authorization duration: 12 months

REAUTHORIZATION CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Documentation of 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. Prescribed by allergist, immunologist or Ear Nose Throat specialist; and

3. Used in combination with another agent for CRSwNP; and
4. No concurrent therapy with any other biologic agents and
5. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Allergic Fungal Rhinosinusitis (AFRS)

INITIAL CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Submission of documentation (e.g., chart notes) confirming diagnosis of allergic fungal rhinosinusitis (AFRS); and
2. Member is 6 years of age or older; and
3. Prescribed by or in consultation with an allergist, immunologist, or Ear Nose Throat specialist; and
4. Member has a history of prior sino-nasal surgery; and
5. Paid claims or submission of documentation (e.g., chart notes) confirming an inadequate response or inability to tolerate at least a 2-month treatment with intranasal corticosteroid (e.g., fluticasone); and
6. No concurrent therapy with any other biologic agents; and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial Authorization duration: 12 months

REAUTHORIZATION CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Documentation of a positive clinical response to therapy (e.g., change in sinus opacification, improvement in nasal congestion/obstruction score [NC; 0-3 scale]); and
2. Prescribed by allergist, immunologist or Ear Nose Throat specialist; and
3. No concurrent therapy with any other biologic agents and
4. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Eosinophilic Esophagitis (EoE)

INITIAL CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Submission of documentation (e.g., chart notes) confirming diagnosis of eosinophilic esophagitis (EoE); and
2. Member has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain);

and

3. Member has at least 15 intraepithelial eosinophils per high power field (HPF); and
4. Other causes of esophageal eosinophilia have been ruled out; and
5. Both of the following:
    1. Member is 1 year of age or older; and
    2. Member weighs at least 15 kg; and
6. Paid claims or submission of documentation (e.g., chart notes) confirming an inadequate response or inability to tolerate at least an 8-week trial of one of the following:
    1. Proton Pump Inhibitors (e.g., pantoprazole, omeprazole); or
    2. Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone); and
7. Prescribed by or in consultation with gastroenterologist or allergist/immunologist; and
8. No concurrent therapy with any other biologic agents; and
9. Dose and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Documentation of a positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline:
    1. Symptoms (e.g., dysphagia, food impaction, heartburn, chest pain); or
    2. Histologic measures (e.g., esophageal intraepithelial eosinophil count); or
    3. Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures); and
2. No concurrent therapy with any other biologic agents; and
3. ONE of the following:

1. Dose and frequency does not exceed maximum FDA recommendation per indication requested; or
2. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Prurigo Nodularis (PN)

INITIAL CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Submission of documentation (e.g., chart notes) confirming a diagnosis of Prurigo Nodularis (PN); and
2. Member is 18 years of age or older; and
3. Member has at least 20 nodular lesions; and
4. Paid claims or submission of documentation (e.g., chart notes) confirming inadequate response or inability to tolerate one previous PN treatment (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin); and
5. Prescribed by or in consultation with allergist/immunologist or dermatologist; and
6. No concurrent therapy with any other biologic agents; and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:
    1. Reduction in the number of nodular lesions from baseline; or
    2. Improvement in symptoms (e.g., pruritus, inflammation) from baseline; and
2. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Chronic obstructive pulmonary disease (COPD)

INITIAL CRITERIA: Dupilumab (Dupixent®) is medically necessary ALL of the following are met:

1. Member is 18 years of age or older; and
2. Submission of documentation (e.g., chart notes) confirming a diagnosis of chronic obstructive pulmonary disease (COPD) and Presence of Type 2 inflammation evidenced by blood eosinophils greater than or equal to 300 cells per microliter at baseline; and
3. Paid claims or submission of documentation (e.g., chart notes) confirming member is currently being treated with ONE of the following or is unable to tolerate these medications:
    1. Triple therapy (i.e., an inhaled corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA) and a long-acting beta agonist (LABA); or
    2. If ICS are contraindicated, a LAMA and a LABA; and
4. Post-bronchodilator forced expiratory volume [FEV1] / forced vital capacity [FVC] ratio less than 0.70 while on an optimized therapy; and
5. Member has had one of the following within the past 12 months:
    1. At least two exacerbations where systemic corticosteroids [intramuscular, intravenous, or oral (e.g., prednisone)] were required at least once; or
    2. COPD-related hospitalization; and
6. Member experiences dyspnea during everyday activities (e.g., needs to stop for breath when walking on level ground); and
7. Prescribed by or in consultation with a pulmonologist; and
8. No concurrent therapy with any other biologic agents; and
9. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Member demonstrates a positive clinical response to therapy (e.g., improved lung function, a reduction in COPD exacerbations); and
2. Member continues to receive one of the following therapies at an optimized dose:
    1. Triple therapy (i.e., an inhaled corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA) and a long-acting beta agonist (LABA); or
    2. If ICS are contraindicated, a LAMA and a LABA; and
3. Prescribed by or in consultation with a pulmonologist; and
4. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Chronic Spontaneous Urticaria (CSU)

INITIAL CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Submission of documentation (e.g., chart notes) confirming a diagnosis of chronic spontaneous urticaria (CSU); and
2. Member is 12 years of age or older; and
3. Documented history of urticaria for at least 6 weeks; and
4. Paid claims or submission of documentation (e.g., chart notes) confirming inadequate response or inability to tolerate a minimum two-week trial of a formulary second generation H1 antihistamine at the maximum tolerated dose; and
5. Prescribed by or in consultation with allergist/immunologist or dermatologist; and
6. No concurrent therapy with any other biologic agents; and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Documentation of a positive clinical response to therapy (e.g., decrease in severe itching or urticaria activity); and
2. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Bullous Pemphigoid

INITIAL CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Submission of documentation (e.g., chart notes) confirming a diagnosis of bullous pemphigoid; and
2. Member is 18 years of age or older; and
3. Member has a Bullous Pemphigoid Disease Area Index (BPDAI) activity score ≥24; and
4. Member has a Peak Pruritus Numeric Rating Scale (NRS) score ≥4; and
5. Used in combination with a tapering course of oral corticosteroids; and
6. Paid claims or submission of documentation (e.g., chart notes) confirming an inadequate response or inability to tolerate at least 3 of the following
    - High potency topical corticosteroids
    - Oral corticosteroids
    - Doxycycline
    - Immunosuppressive therapies (ex. azathioprine, mycophenolate, methotrexate, etc.); and
7. Prescribed by or in consultation with allergist/immunologist or dermatologist; and
8. No concurrent therapy with any other biologic agents; and
9. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Dupilumab (Dupixent®) is medically necessary when ALL of the following are met:

1. Documentation of a positive clinical response to therapy (e.g., sustained remission, improvement in Peak Pruritus NRS score); and
2. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

P&T Approval Date: 05/2026

Field Name	Field Description
Prior Authorization Group Description	**Duvyzat**
Drugs	Duvyzat (givinostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or provider who specializes in the treatment of Duchenne Muscular Dystrophy (DMD)
Coverage Duration	If all the criteria are met, the initial request will be approved for 12 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 2/2026	**Initial Authorization:** • Medication is prescribed at an FDA approved dose according to body weight • Genetically confirmed diagnosis of DMD and copies of testing were submitted with request • Patient has been stable on baseline corticosteroids for at least 6 months • Patient is ambulatory • Patient's platelet count is $\geq 150 \times 10^9$/L **Re-Authorization:** • Documentation or provider attestation of positive clinical response (such as improved muscle function, muscle strength, or disease stabilization) • Patient is on concurrent corticosteroid treatment • Patient is ambulatory • Medication is prescribed at an FDA approved dose according to body weight **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Title: Elagolix sodium (Orilissa™)

Applicable Drugs:

Brand Name	Generic Name
Orilissa™	Elagolix

Policy:

<u>*Requests for treatment of gender dysphoria are excluded from benefit coverage for members under the age of 19*</u>

Elagolix (Orilissa™) is medically necessary when all of the following are met:

1. Diagnosis of moderate to severe pain associated with endometriosis; and
2. Member is 18 years of age or older; and
3. ONE of the following:
    a. Inadequate response or inability to tolerate BOTH of the following:
        1. One non-steroidal anti-inflammatory drug; and
        2. Contraceptives; or
    b. Member has had surgical ablation to prevent recurrence

Authorization duration: 2 years

Coverage duration is limited to:

1. 24 months/ lifetime for 150mg tablet
2. 6 months/ lifetime for 200mg tablet

All other treatment durations are considered Experimental/ Investigational.

P&T Approval Date: 10.2026

Title: Elagolix/estradiol/norethindrone acetate (Oriahnn)/Relugolix, estradiol and norethindrone (Myfembree)

Applicable Drugs:

Brand Name	Generic Name
Oriahnn	Elagolix, estradiol, norethindrone acetate
Myfembree	Relugolix, estradiol, norethindrone acetate

Policy:
Exclusion Criteria: pregnancy, history of osteoporosis, and history of hepatic impairment

Heavy Menstrual Bleeding Associated with Uterine Leiomyomas
INITIAL CRITERIA: Elagolix/estradiol/norethindrone acetate (Oriahnn®) or Relugolix/estradiol/norethindrone acetate (Myfembree®) is medically necessary when ALL of the following are met:

1. Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and
2. Member is premenopausal; and
3. One of the following:
    1. Inadequate response after at least 3 months OR inability to tolerate ONE of the following:
        1. Combination (estrogen/progestin) contraceptive; or
        2. Progestins; or
    2. Member has had a previous interventional therapy to reduce bleeding (e.g., uterine-artery embolization and magnetic resonance-guided focused ultrasonography); and
4. Treatment duration has not exceeded a total of 24 months

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Elagolix/estradiol/norethindrone acetate (Oriahnn®) or Relugolix/estradiol/norethindrone acetate (Myfembree®) is medically necessary when BOTH of the following are met:

1. Member has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.); and
2. Treatment duration has not exceeded a total of 24 months

Reauthorization duration: 12 months

Pain Associated with Endometriosis
INITIAL CRITERIA: Relugolix/estradiol/norethindrone acetate (Myfembree®) is medically necessary when ALL of the following are met:

1. Diagnosis of moderate to severe pain associated with endometriosis; and

2. Member is premenopausal; and
3. One of the following:
    1. Inadequate response after at least 3 months or inability to tolerate one of the following:
        1. Danazol; and
        2. Combination (estrogen/progestin) contraceptive; and
        3. Progestins; or
    2. Member has had surgical ablation to prevent recurrence; and
4. Treatment duration has not exceeded a total of 24 months

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Relugolix/estradiol/norethindrone acetate (Myfembree®) is medically necessary when BOTH of the following are met:

1. Member has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and non-menstrual pelvic pain); and
2. Treatment duration has not exceeded a total of 24 months

Reauthorization duration: 12 months

Coverage duration is limited to 24 months/lifetime
All other treatment durations are considered experimental/investigational.

P&T Approval Date: 11/2025

Title: Epinephrine Products

Applicable Drugs:

Brand Name	Generic Name
Auvi-Q, EpiPen, EpiPen Jr, Neffy	Epinephrine

Policy:

Auvi Q®, EpiPen®, EpiPen Jr.®, Neffy® is approved when ALL of the following are met:

1. ONE of the following:
    1. Documentation of a demonstrated inability to use one chemically equivalent generic agent; or
    2. The member has a genuine allergic reaction to an inactive ingredient in generic agent(s) (allergic reaction(s) must be clearly documented in the patient's medical record); and
2. For Auvi Q® and Neffy® only, documentation that the member or the member's caregivers would be unable to utilize the alternative epinephrine auto-injector devices (e.g., epinephrine) due to significant visual, physical, or functional impairment

Approval duration: 2 years

P&T Approval Date: 2/2026

Title: Excluded medications with no significant advantage over covered alternatives

Applicable Drugs:

N/A

Policy:
Coverage is subject to the terms, conditions, and limitations of the member's contract.

The medications listed below do not meet medical necessity, as defined in the member's benefits book, and will be excluded from coverage (not covered) under the prescription drug benefit.

Drug	Components	Rationale
Ibuprofen/famotidine (Duexis®)	Ibuprofen 800mg/ famotidine 26.6mg tablet	Combination of ibuprofen and famotidine; no advantage over the individual components
Metformin modified, extended release (Glumetza®)	Metformin modified, extended release 500mg, 1000mg tablet	Extended-release formulation of metformin; other extended release products are available
Naproxen/esomeprazole (Vimovo®)	Naproxen 500mg/ esomeprazole 20mg tablet Naproxen 375mg/ esomeprazole 20mg tablet	Combination of naproxen and esomeprazole; no advantage over the individual components; esomeprazole 20mg is available over the counter
Omeprazole/aspirin (Yosprala®)	Omeprazole 40mg/ aspirin 81mg tablet Omeprazole 40mg/ aspirin 325mg tablet	Combination of aspirin and omeprazole; no advantage over the individual components
Omeprazole/sodium bicarbonate capsules 40mg/1100mg (Zegerid capsules® 40mg/1100mg)	Omeprazole 40mg/ sodium bicarbonate 1100mg	Combination of omeprazole and sodium bicarbonate offers no advantage over the individual components,

		omeprazole alone, or other proton pump inhibitors
Vanos®	Fluocinonide 0.1% Cream	High Potency Alternatives Available: Clobetasol Propionate, Augmented Betamethasone, Halobetasol
Prenatal Vitamins, Azesco®, Ziphex®, Pregenna®/PNV® Tab, Zalvit®, DermacinRx Tab Pretrate®	Prenatal Vitamins and Minerals With Folic Acid And Iron (Various Dose Combinations)	Multiple Generic, Prescription Strength Prenatal Vitamins Are Available
Chlorzoxazone 250 Mg	Chlorzoxazone 250 Mg	Chlorzoxazone 500mg Tablet Is Functionally Scored to Be Broken In Half
Vanadom®	Carisoprodol 350 Mg	Alternatives Available: Carisoprodol 350mg, Tizanidine, Cyclobenzaprine, Baclofen, Methocarbamol, Chlorzoxazone 500mg
Diclofenac potassium (Lofena) 25mg tablet	Diclofenac potassium 25mg tablet	Alternatives available: diclofenac potassium 50mg, diclofenac sodium delayed release, ibuprofen, naproxen sodium, meloxicam, celecoxib, indomethacin
Methocarbamol 1000mg tab, Tanlor®	Methocarbamol 1000mg tab	Methocarbamol 500mg tablets available. Alternatives available: carisoprodol 350mg, tizanidine, cyclobenzaprine, methocarbamol 500 and 750mg, chlorzoxazone 500mg

P&T Approval Date: 11/2025

Prior Authorization Group Description	**Familial Chylomicronemia Syndrome**
Drugs	Tryngolza (olezarsen), Redemplo (plozasiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, lipidologist, or cardiologist or specialist experienced in familial chylomicronemia syndrome (FCS)
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	• Medication is prescribed at an FDA approved dose
	• The member has undergone genetic testing to confirm a diagnosis of FCS with ONE of the following results:
	  ○ The member has a pathogenic gene mutation in FCS-causing genes (e.g., *LPL*, *GPIHBP1*, *APOA5*, *APOC2*, or *LMF1*)
	  ○ The member has inconclusive genetic results and has documentation supporting the diagnosis of FCS by ONE of the following:
	  ▪ North America Familial Chylomicronemia Syndrome (NAFCS) score ≥ 45
	  ▪ FCS score ≥ 10
	  ▪ History of acute pancreatitis
	  ▪ History of recurrent abdominal pain without other known causes
	• The member's most recent triglyceride level is ≥880 mg/dL (10 mmol/L)
	• The member is refractory to standard triglyceride lowering therapies (e.g., statins, fibrates, omega-3 fatty acids, and niacin)
	• The prescriber attests the member will follow a low-fat diet
	•
	
	Re-Authorization:
	• Medication is prescribed at an FDA approved dose
	• Documentation of a positive clinical benefit (e.g., reduction in fasting triglyceride level from baseline, fewer acute pancreatitis events)
	• The prescriber attests the member will continue to follow a low-fat diet

Review/Revision Date: 05/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: FDA Approved Medications Deemed Experimental Investigational

Applicable Drugs:

Brand Name	Generic Name

*Oncology agents are exempt from the review because they are subjected to medical necessity review per criteria established for oncology agents. Line extensions of existing medications using the same brand name and has the same indication are exempt from the review.

Policy:
Prescription drugs or biologics* that are approved by the FDA under the accelerated approval process are subjected to review to determine if the surrogate or intermediate clinical endpoint used in the trial is an acceptable measure of the drug or biologic's efficacy in the condition for which it is approved, and thus medically necessary. If an FDA approved drug or biologic does not demonstrate efficacy for the disease it is approved to treat, then the drug or biologic is determined to be experimental/investigational, despite FDA approval and is therefore not a covered benefit. Medical necessity is defined in the member's benefits book. Medications that do not meet the definition of medical necessity are excluded from coverage under the prescription drug benefit.

A prescription drug or biologic* is considered medically necessary when the following are met:

1. The prescription drug or biologic* must have final approval from the FDA with the following statement in the label *This indication is approved under accelerated approval based on [surrogate marker used in the clinical trial(s)]. Continued approval for this indication may be contingent upon verification of clinical benefit in the confirmatory trial(s).;* and
2. The scientific evidence must permit conclusions concerning the effect of the prescription drug or biologic on health outcomes; and
3. The prescription drug or biologic must improve the net health outcome; and
4. The prescription drug or biologic must be as beneficial as any established alternatives; and
5. The improvement must be attainable outside the investigational settings.

The medications listed below do not meet medical necessity, as defined in the member's benefits book, and will be excluded from coverage (not covered) under the prescription drug benefit.

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Fecal Microbiota**
Drugs	Rebyota (fecal microbiota, live-jslm) Vowst (fecal micromiota spores, live-brpk)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Treatment of Clostridioides difficile infection (CDI)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the request will be approved for 1 treatment course
Other Criteria Review/Revision Date: 11/2025	• Medication is prescribed at an FDA approved dose • Diagnosis of at least 1 recurrent episode of CDI (≥2 total CDI episodes) • Current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days) • Positive stool test for C. difficile within 30 days before prior authorization request • Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment • For Vowst only: attestation patient will bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst *Rebyota and Vowst are limited to 1 treatment course* **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Title: Fezolinetant (Veozah)

Applicable Drugs:

Brand Name	Generic Name
Veozah™	**Fezolinetant**

Policy:
INITIAL CRITERIA: Fezolinetant (Veozah™) is medically necessary when all of the following are met:

1. Diagnosis moderate to severe vasomotor symptoms due to menopause; and
2. Inadequate response or inability to tolerate a minimum 30-day supply of both of the following:
    a. Menopausal hormone therapy (e.g., generic estradiol vaginal cream, generic estradiol vaginal tablet); and
    b. Non-hormonal therapy (e.g., paroxetine mesylate, venlafaxine hcl, clonidine, etc.)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Fezolinetant (Veozah™) is medically necessary with documentation of positive clinical response to therapy (e.g., decrease in frequency and severity of vasomotor symptoms from baseline, etc.)

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Title: Finerenone (Kerendia)

Applicable Drugs:

Brand Name	Generic Name
Kerendia®	finerenone

Policy:

INITIAL CRITERIA Finerenone (Kerendia®) is approved when ALL of the following are met:

For Chronic Kidney Disease (CKD) Associated with Type 2 Diabetes (T2DM):

1. Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D); and
2. Urine albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g; and
3. Estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m2; and
4. Serum potassium level less than or equal to 5.0 mEq/L prior to initiating treatment; and
5. Member is 18 years of age or older; and
6. One of the following:
    1. Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with ONE of the following:
        1. Generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril); or
        2. Generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan); or
        3. Sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., Jardiance, Farxiga); or
    2. Member has contraindication or intolerance to ACE inhibitors, ARBs or SGLT2; and

For Heart Failure with Left Ventricular Ejection Fraction >40%:

1. Documentation of diagnosis of heart failure with left ventricular ejection fraction ≥40%
2. Documentation of all of the following:
    a. serum potassium levels ≤5.0 mEq/L
    b. eGFR greater than or equal to 25 ml/min/1.73 m^2

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Finerenone (Kerendia®) is re-approved with documentation of positive clinical response to therapy (e.g., reduced incidence of a sustained declined in eGFR, kidney failure, or renal death)

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Formulary Exception Policy

Applicable Drugs:

N/A

Policy:

Tier Exceptions:

A non-preferred drug will be covered at the preferred tier for brand medications as listed below when there is documentation of inadequate response or inability to tolerate at least three preferred or generic tier alternatives in the same pharmacological class*. Reasonably equivalent therapeutic class alternatives will be considered when there are limited pharmacological class alternatives available.

1. Brand medication to preferred brand tier or
2. Generic medication to generic tier

Non-formulary Exceptions:

A non-formulary drug is medically necessary when ONE of the following are met:

1. $0 cost-share will apply when BOTH of the following are met:
    a. The drug is described as either a preventative medication identified by the US Preventive Services Task Force (USPSTF) or Women's Preventive Services provision of the Patient Protection and Affordable Care Act (PPACA); and if applicable; and
    b. For branded products, ALL of the following:
        1. Inadequate response or inability to tolerate the generic equivalent, if available; and
        2. Inadequate response or inability to tolerate a formulary alternative; and
        3. The prescriber has provided documentation indicating the requested product is medically necessary; or
2. Appropriate level of cost share will apply when BOTH of the following are met:
    a. FDA approved, or compendia supported use; and
    b. ONE of the following:
        1. If biosimilar of the requested reference product or generic equivalent of the requested brand is available, both of the following:
            1. There is documentation of inadequate response or inability to tolerate biosimilar of the requested reference product or generic equivalent of the requested brand; and
            2. There is documentation of inadequate response or inability to tolerate at least two formulary alternatives in the same pharmacological class*. Reasonably equivalent therapeutic class alternatives will be considered when there are limited pharmacological class alternatives available. Safety edits (age and quantity limits) will apply to non-formulary requests; or

2. If biosimilar of the requested reference product or generic equivalent of the requested brand is NOT available: there is documentation of inadequate response or inability to tolerate at least three formulary alternatives in the same pharmacological class*. Reasonably equivalent therapeutic class alternatives will be considered when there are limited pharmacological class alternatives available. Safety edits (age and quantity limits) will apply to non-formulary requests

CHIP (IN Focus ID 10093453)

A brand medication may be covered at the generic benefit level when there is documentation of an inadequate response or inability to tolerate at least three ~~generic~~ formulary alternatives in the same pharmacological class*. Reasonably equivalent therapeutic class alternatives will be considered when there are limited pharmacological class alternatives available.

Compounded Products:

A non-preferred compounded product may be covered at the preferred (formulary) tier when there is an inadequate response or inability to tolerate/use all other formulary alternatives.

Note: Compounded products are specially made products to meet the needs of an individual member and are not considered generics and thus not eligible for an exception to the generic tier.

$0 Cost-Share Override

An exception to allow no-cost share is medically necessary when:

1. The drug is described as either a preventative medication identified by the US Preventive Services Task Force (USPSTF) or Women's Preventive Services provision of the Patient Protection and Affordable Care Act (PPACA); and if applicable
2. For branded products, ALL of the following:
    1. Inadequate response or inability to tolerate the generic equivalent, if available
    2. Inadequate response or inability to tolerate a formulary alternative
    3. The prescriber has provided documentation indicating the requested product is medically necessary

**If there are fewer than three alternatives, all alternatives in the pharmacological class must be considered.*

Premium Formulary: This policy does not apply to the premium formulary.

Authorization duration: 1 years

P&T Approval Date: 11/2025

Prior Authorization Group Description	**Forzinity (elamipretide)**
Drugs	Forzinity (elamipretide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a cardiologist, endocrinologist, hematologist, geneticist, neurologist, or other provider specializing in the treatment of Barth Syndrome.
Coverage Duration	If all of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date: 02/2026	**Initial Authorization:** • Diagnosis of Barth Syndrome confirmed via identification of mutations in the TAZ gene per genetic testing • Member's current weight is provided with the request and is ≥ 30 kg • Pediatrics: patient does not have renal impairment • Adults: patient is not on dialysis • Requested dose is within FDA approved dosing guidelines **Reauthorization:** • Patient has not experienced a serious hypersensitivity reaction to Forzinity • Documentation or provider attestation of clinical benefit (i.e. 6-minute walk test, Total Fatigue Score on the Barth syndrome Symptom Assessment, muscle strength, cardiac function, etc.) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Fosdenopterin (Nulibry™)

Applicable Drugs:

Brand Name	Generic Name
Nulibry®	Fosdenopterin

Policy:
INITIAL CRITERIA Fosdenopterin (Nulibry™) is medically necessary when ALL of the following are met:

1. One of the following:
    a. Presumed diagnosis of molybdenum cofactor (MoCD) Type A deficiency; or
    b. Diagnosis of molybdenum cofactor (MoCD) Type A deficiency confirmed by genetic test; and
2. Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Fosdenopterin (Nulibry™) is medically necessary when ALL of the following are met:

1. Diagnosis of molybdenum cofactor (MoCD) Type A deficiency as confirmed by genetic test [if not previously confirmed]; and
2. Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders; and
3. Document of positive clinical response to therapy (e.g., reduction in urine concentrations of S-sulfocysteine (SSC))

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Fostemsavir (Rukobia), Enfuvirtide (Fuzeon)

Applicable Drugs:

Brand Name	Generic Name
Rukobia®	Fostemsavir
Fuzeon®	Enfuvirtide

Policy:
INITIAL CRITERIA: Fostemsavir (Rukobia®) is approved when ALL of the following are met:

1. Diagnosis of HIV-1; and
2. Member is 18 years of age or older; and
3. Will be used in combination with other antiretroviral(s); and
4. Member is treatment-experienced with multi-drug resistant HIV-1 infection; and
5. Member is failing their current antiretroviral regimen due to resistance, intolerance, or safety concerns.

Initial Authorization duration: 12 months

CONTINUATION CRITERIA: Fostemsavir (Rukobia®) is re-approved when there is documentation of positive clinical response to therapy (e.g., decrease in viral load from baseline; HIV-1 RNA <200 copies/mL was achieved; increase in CD4+ cell count over time)

Continuation authorization duration: 2 years

INITIAL CRITERIA: Enfuvirtide (Fuzeon®) is approved when ALL of the following are met:

1. Diagnosis of HIV-1; and
2. Member weighs at least 11kg; and
3. Will be used in combination with other antiretroviral(s); and
4. Member is treatment experienced; and
5. Member is experiencing HIV-1 replication despite ongoing antiretroviral therapy

Initial authorization duration: 12 months

CONTINUATION CRITERIA: Enfuvirtide (Fuzeon®) is re-approved when there is documentation of positive clinical response to therapy (e.g., decrease in viral load from baseline; HIV-1 RNA <200 copies/mL was achieved; increase in CD4+ cell count over time)

Continuation authorization duration: 2 years

P&T Approval Date: 11/2025

Title: Gabapentin (Gralise/Horizant)/pregabalin (Lyrica CR)

Applicable Drugs:

Brand Name	Generic Name
Gralise®	gabapentin
Horizant®	Gabapentin enacarbil
Lyrica CR®	pregabalin controlled-release

Policy:

Post-herpetic neuralgia

INITIAL CRITERIA: Gabapentin (Gralise®), gabapentin (Horizant®) or pregabalin (Lyrica CR®) is approved when all of the following are met:

1. Diagnosis of post-herpetic neuralgia, and
2. Member is 18 years of age or older; and
3. Inadequate response or inability to tolerate ONE of the following:
    1. Gabapentin; or
    2. Pregabalin

Initial Authorization duration: 2 years

REAUTHORIZATION CRITERIA: Gabapentin (Gralise®), or gabapentin enacarbil (Horizant®), or Pregabalin (Lyrica CR®) is re-approved when there is positive clinical response to therapy.

Reauthorization duration: 2 years

Restless legs syndrome

INITIAL CRITERIA: Gabapentin enacarbil (Horizant®) is approved ALL of the following are met:

1. Diagnosis of moderate-to-severe primary restless legs syndrome; and
2. Inadequate response or inability to tolerate BOTH of the following:
    1. Pramipexole; and
    2. Ropinirole; and
3. Member is 18 years of age or older

Initial Authorization duration: 2 years

REAUTHORIZATION CRITERIA Gabapentin enacarbil (Horizant®) is re-approved when there is positive clinical response to therapy.

Reauthorization duration: 2 years

Diabetic peripheral neuropathy

INITIAL CRITERIA: Pregabalin (Lyrica CR®) is approved when ALL of the following are met:

1. Diagnosis of neuropathic pain associated with diabetic peripheral neuropathy; and
2. Inadequate response or inability to tolerate ONE of the following:
    1. Gabapentin; or
    2. Pregabalin; and
3. Member is 18 years of age or older

Initial Authorization duration: 2 years

REAUTHORIZATION CRITERIA Pregabalin (Lyrica CR®) is re-approved when there is positive clinical response to therapy.

Reauthorization duration: 2 years

P&T Approval Date: 2/2026

Title: Galafold

Applicable Drugs:

Brand Name	Generic Name
Galafold	migalastat

Policy:
INITIAL CRITERIA: Galafold™ (migalastat) is medically necessary when all of the following are met:

1. Diagnosis of Fabry disease; and
2. Member is 18 years of age or older; and
3. Member has an amenable galactosidase alpha gene (GLA) variant (per FDA labeling information) based on in vitro assay data; and
4. Galafold will not be used in combination with other drug(s) indicated for the treatment of Fabry disease (e.g., Fabrazyme)

Initial Authorization duration: 6 months

REAUTHORIZATION CRITERIA: Galafold™ (migalastat) is medically necessary when both of the following are met:

1. Documentation of positive clinical response to therapy [e.g., 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, or improvement and/or stabilization in symptoms (e.g., renal function, neuropathic pain)], and
2. Galafold will not be used in combination with other drug(s) indicated for the treatment of Fabry disease (e.g., Fabrazyme)

Reauthorization duration: 1 years

P&T Approval Date: 11/2025

Title: Ganaxolone (Ztalmy®)

Applicable Drugs:

Brand Name	Generic Name
Ztalmy®	Ganaxolone

Policy:

INITIAL CRITERIA Ganaxolone (Ztalmy®) is approved when ALL of the following are met:

1. Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD); and
2. Documentation of mutation in the CDKL5 gene; and
3. Member is experiencing motor seizures (e.g., bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, focal, or bilateral tonic-clonic); and
4. One of the following:
    1. Inadequate response or inability to tolerate two formulary anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine); or
    2. Continuation of therapy with requested medication; and
5. Member is 2 years of age or older; and
6. Prescribed by or in consultation with a neurologist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Ganaxolone (Ztalmy®) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy (e.g., reduction in frequency of major motor seizures compared to baseline); and
2. Prescribed by or in consultation with a neurologist

Reauthorization duration: 2 years

P&T Approval Date: 2/2026

Field Name	Field Description
Prior Authorization Group Description	Gender Dysphoria Exclusion
Drugs	Puberty blocking medications (Supprelin, Lupron, etc.) and hormone replacement therapy (Estradiol, Testosterone, etc.) used for treatment of gender dysphoria
Exclusion Criteria	Treatment of gender dysphoria
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	N/A
Coverage Duration	N/A
Other Criteria Date: 10/2026	**Initial Authorization:** • Requests for treatment of gender dysphoria are excluded from benefit coverage for children under the age of 19 **Re-Authorization:** • Requests for treatment of gender dysphoria are excluded from benefit coverage for children under the age of 19 Final Rule: Prohibition on Federal Medicaid and CHIP Funding for Sex Rejecting Procedures Furnished to Children and Youth (CMS-2451-F) | Guidance Portal [hhs.gov]

Prior Authorization Group Description	**Gene Therapies for Spinal Muscular Atrophy**
Drugs	Zolgensma (onasemnogene abeparvovec-xioi) Itvisma (onasemnogene abeparvovec-brve)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Member has previously received this Zolgensma or Itvisma • Advanced spinal muscular atrophy (SMA) (e.g., complete paralysis of limbs, permanent ventilator-dependence) • Administration to premature neonates before reaching full-term gestational age
Required Medical Information	N/A
Age Restrictions	Zolgensma: Member must be less than 2 years of age Itvisma: Patient must be 2 to less than 18 years of age
Prescriber Restrictions	Prescribed by a neurologist
Coverage Duration	If all of the criteria are met, ONE dose may be approved. Reauthorization is not permitted. **The safety and effectiveness of repeat administration of Zolgensma and Itvisma have not been evaluated and will not be approved.**
Other Criteria Revision/Review Date: 02/2026	Patient must meet all of the following criteria: <u>For Zolgensma</u> • Diagnosis of Spinal Muscular Atrophy (SMA) • Bi-allelic mutations in the survival motor neuron 1 (SMN1) gene • Documentation is provided that the member has 3 or fewer copies of the SMN2 gene • Member's body weight • Baseline anti-AAV9 antibody titers of ≤1:50 measured using an enzyme-linked immunosorbent assay (ELISA) • Dosing is consistent with FDA approved labeling <u>For Itvisma</u> • Diagnosis of Spinal Muscular Atrophy (SMA) • Confirmed mutation in the survival motor neuron 1 (SMN1) gene • Onset of clinical signs and symptoms at ≥ 6 months of age • Patient is able to sit independently, but has never had the ability to walk independently • Baseline anti-AAV9 antibody titers of ≤1:50 measured using an enzyme-linked immunosorbent assay (ELISA) • Documentation is provided that the member has 3 or fewer copies of the SMN2 gene • Dosing is consistent with FDA approved labeling **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Generalized Pustular Psoriasis (GPP) Agents**
Drugs	Spevigo (spesolimab-abzo)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or geneticist
Coverage Duration	Acute Flares (IV vial): If all of the criteria are met, the request will be approved for up to 2 doses. Maintenance Treatment (SQ syringe): If all criteria are met, the initial request will be approved for 12 months. Reauthorization requests will be approved for 12 months.
Other Criteria Date: 05/2026	**Initial Authorization** • Diagnosis of generalized pustular psoriasis (GPP) • If request is for an acute GPP flare (IV vial), member must be experiencing an acute flare of GPP of moderate to severe intensity as defined by having all of the following: o Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 or greater o Presence of fresh pustules (new appearance or worsening of pustules) o GPPPGA pustulation sub score of 2 or greater o At least 5% of body surface area covered with erythema and the presence of pustules • If request is for maintenance treatment of GPP (SQ syringe), member must have all of the following: o History of at least two GPP flares in the past year of moderate to severe intensity o GPPPGA score of 0 or 1 o Documented trial and failure, intolerance, or contraindication to TWO of the following: oral retinoids, methotrexate, and cyclosporine • Medication is prescribed at an FDA approved dose **Reauthorization** • If request is for an acute GPP flare (IV vial), member must have achieved a clinical response, defined as achieving a GPPPGA score of 0 or 1, to previous treatment and is now experiencing a new flare • If request is for maintenance treatment of GPP (SQ syringe), member must have documentation of positive clinical response to therapy (i.e., reduction in GPP flares) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Title: Glucagon-like peptide (GLP-1) Receptor Agonist For Type 2 Diabetes Mellitus

Applicable Drugs:

Brand Name	Generic Name
n/a	Exenatide
Mounjaro™	Tirzepatide
Ozempic®; Rybelsus®	Semaglutide
Trulicity®	Dulaglutide
Victoza®	liraglutide

Policy:
INITIAL CRITERIA: Exenatide, , tirzepatide (Mounjaro™), semaglutide (Ozempic®), semaglutide (Rybelsus®), dulaglutide (Trulicity®), liraglutide is medically necessary when ONE of the following are met:

1. Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus; or
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:
    1. A1c greater than or equal to 6.5%; or
    2. Fasting plasma glucose (FPG) greater than or equal to 126mg/dL; or
    3. 2-hour plasma glucose (PG) greater than or equal to 200mg/dL during OGTT (oral glucose tolerance test); or
    4. Random plasma glucose greater than or equal to 200mg/dL

Initial authorization duration: 1 year

INITIAL CRITERIA Brand Victoza® is medically necessary when ALL of the following are met:

1. ONE of the following:
    1. Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus; or
    2. Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidence by one of the following laboratory values:
        1. A1c greater than or equal to 6.5%; or
        2. Fasting plasma glucose (FPG) greater than or equal to 126mg/dL; or
        3. 2-hour plasma glucose (PG) greater than or equal to 200mg/dL during OGTT (oral glucose tolerance test); or
        4. Random plasma glucose greater than or equal to 200mg/dL; and
2. Submission of documentation (e.g., chart note) confirming inadequate response or inability to tolerate a minimum 90-day supply of TWO of the following:

1. Exenatide
2. Ozempic
3. Trulicity
4. Rybelsus
5. Mounjaro

Initial authorization duration: 1 year

REAUTHORIZATION CRITERIA Exenatide (Byetta), exenatide ER (Bydureon/Bydureon BCise), tirzepatide (Mounjaro), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity), liraglutide (Victoza)~~,~~ is medically necessary when ALL of the following are met:

1. Documentation of positive clinical response to therapy (e.g., reduction in A1c); and
2. For Brand Victoza only, submission of documentation (e.g., chart note) confirming inadequate response or inability to tolerate a minimum 90-day supply of TWO of the following:
    1. Exenatide
    2. Ozempic
    3. Trulicity
    4. Rybelsus
    5. Mounjaro

Reauthorization duration: 1 year

P&T Approval Date: 11/2025

Title: Growth Hormones

Applicable Drugs:

Brand Name	Generic Name
Genotropin®	Somatropin
Humatrope®	Somatropin
Norditropin®	Somatropin
Nutropin®/Nutropin® AQ	Somatropin
Omnitrope®	Somatropin
n/a	Somatropin
Serostim®	Somatropin
Zomacton®	Somatropin
n/a	Somatropin
Skytrofa®	Lonapegsomatropin-tcgd
Sogroya®	Somapacitan-beco
Ngenla®	Somatrogon-ghla

Policy:

A. Children with idiopathic short stature

INITIAL CRITERIA Somatropin (Omnitrope®, Humatrope®, Genotropin®, Nutropin®[AQ], Norditropin®, or Zomacton®) is medically necessary when all of the following are met:

1. Prescribed by an endocrinologist; and
2. Height less than or equal to 2.25 standard deviations from the mean (1.2 percentile); and
3. Documentation of growth velocity; and
4. Epiphyses are not closed; and
5. For Humatrope®, Genotropin®, Zomacton® only, inadequate response or inability to tolerate ONE of the following:
    a. Nutropin®/Nutropin AQ®; or
    b. Norditropin®; or
    c. Omnitrope®

Initial authorization duration: 1 year

CONTINUATION CRITERIA Somatropin (Omnitrope®, Humatrope®, Genotropin®, Nutropin®[AQ], Norditropin®, or Zomacton®) is medically necessary when all of the following are met:

1. Growth velocity increased by at least 50 percent from baseline; and
2. For Humatrope®, Genotropin®, Zomacton® only, inadequate response or inability to tolerate ONE of the following:
    a. Nutropin®/Nutropin AQ®; or
    b. Norditropin®; or
    c. Omnitrope®; and
3. Yearly evaluation by an endocrinologist

Continuation authorization duration: 1 year

B. Turner Syndrome

INITIAL CRITERIA Somatropin (Humatrope®, Genotropin®, Norditropin®, Nutropin®[AQ], Omnitrope® or Zomacton®) is medically necessary when all of the following are met:

1. Diagnosis of Turner syndrome (Gonadal Dysgenesis); and
2. Prescribed by an endocrinologist; and
3. Height is below the 5th percentile on growth charts for age and gender; and
4. For Humatrope®, Genotropin®, Zomacton® only, inadequate response or inability to tolerate ONE of the following:
    a. Norditropin®; or
    b. Nutropin®/Nutropin AQ®; or
    c. Omnitrope®

Initial authorization duration: 1 year

CONTINUATION CRITERIA Somatropin (Humatrope®, Genotropin®, Norditropin®, Nutropin®[AQ], Omnitrope® or Zomacton®) is medically necessary when all of the following are met:

1. For Humatrope®, Genotropin®, Zomacton® only, inadequate response or inability to tolerate ONE of the following:
    a. Nutropin®/Nutropin AQ®; or
    b. Norditropin®; or
    c. Omnitrope®; and
2. Yearly evaluation by an endocrinologist

Continuation authorization duration: 1 year

C. Growth Hormone deficiency in children

INITIAL CRITERIA: Somatropin (Omnitrope, Norditropin®, Genotropin®, Humatrope®, Saizen®,

Nutropin® [AQ], Zomacton®) somapacitan-beco (Sogroya®), somatrogon-ghla (Ngenla®) or lonapegsomatropin-tcgd (Skytrofa™) is medically necessary when all of the following are met:

1. Prescribed by an endocrinologist; and
2. Growth velocity less than or equal to 5 cm/year after 2 years of age; and
3. Bone age determination documented; and
4. Either ONE of the following responses from provocative testing:
    a. Abnormal response on insulin-induced hypoglycemia test (less than 5 ng/ml); or
    b. Abnormal response of less than 10 ng/ml to any other two provocative tests (performed sequentially, not simultaneously), such as but not limited to levodopa and clonidine; and
5. For Genotropin®, Humatrope®, Saizen®, Zomacton®, somapacitan-beco (Sogroya®) only, inadequate response or inability to tolerate ONE of the following:
    a. Norditropin®; or
    b. Nutropin®/Nutropin AQ®; or
    c. Omnitrope®; and
6. For somapacitan-beco (Sogroya®) only, inadequate response or inability to tolerate BOTH of the following:
    a. somatrogon-ghla (Ngenla®); and
    b. lonapegsomatropin-tcgd (Skytrofa™)

Initial authorization duration: 1 year

CONTINUATION CRITERIA: Somatropin (Omnitrope®, Norditropin®, Genotropin®, Humatrope®, Saizen®, Nutropin®[AQ], Zomacton®), somapacitan-beco (Sogroya®), somatrogon-ghla (Ngenla®) or lonapegsomatropin-tcgd (Skytrofa™) is medically necessary when all of the following are met:

1. For Genotropin®, Humatrope®, Saizen®, Zomacton®, somapacitan-beco (Sogroya®) only, inadequate response or inability to tolerate ONE of the following:
    a. Nutropin®/Nutropin AQ®; or
    b. Norditropin®; or
    c. Omnitrope®; and
2. For somapacitan-beco (Sogroya®) only, inadequate response or inability to tolerate BOTH of the following:
    a. somatrogon-ghla (Ngenla®); and
    b. lonapegsomatropin-tcgd (Skytrofa™); and
3. Yearly evaluation by an endocrinologist

Continuation authorization duration: 1 year

D. Growth hormone deficiency in adults with adult-onset hypothalamic or pituitary disease OR Replacement of endogenous growth hormone (GH) deficiency

INITIAL CRITERIA: Somatropin (Omnitrope®, Norditropin®, Genotropin®, Humatrope®, Saizen®, Nutropin®[AQ], Zomacton®), somapacitan-beco (Sogroya®) is medically necessary when all of the following are met:

1. Prescribed by an endocrinologist; and
2. Clinical history of adult-onset hypothalamic or pituitary disease of organic origin or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage); and
3. Deficiency in any two of the following:
    a. Follicle-stimulating hormone (FSH) and luteinizing hormone (LH) (demonstrated by a low early morning serum testosterone concentration or a low serum estradiol concentration while FSH and LH concentrations are not elevated); or
    b. Thyroid-stimulating hormone (TSH) (demonstrated by a low serum T4 concentration and TSH concentration that is not elevated); or
    c. Adrenocorticotropic hormone (ACTH) (demonstrated by a low early morning serum cortisol and an ACTH that is not elevated); an
4. GH response of less than 5 ng/ml to insulin-induced hypoglycemia; and
5. For Genotropin®, Humatrope®, Saizen®, Zomacton®, Sogroya® only, inadequate response or inability to tolerate ONE of the following:
    a. Norditropin®; or
    b. Nutropin®/Nutropin AQ®; or
    c. Omnitrope®

Initial authorization duration: 1 year

CONTINUATION CRITERIA: Somatropin (Omnitrope®, Norditropin®, Genotropin®, Humatrope®, Saizen®, Nutropin®[AQ], Zomacton®), somapacitan-beco (Sogroya®) is medically necessary when all of the following are met:

1. For Genotropin®, Humatrope®, Saizen®, Zomacton®, Sogroya® only, inadequate response or inability to tolerate ONE of the following:
    a. Nutropin®/Nutropin AQ®; or
    b. Norditropin®; or
    c. Omnitrope®; and
2. Yearly evaluation by an endocrinologist

Continuation authorization duration: 1 year

E. Growth Hormone deficiency in adults with childhood onset hypothalamic or pituitary disease

INITIAL CRITERIA Somatropin (Omnitrope®, Norditropin®, Genotropin®, Humatrope®, Saizen®, Nutropin® [AQ] is medically necessary when all of the following are met:

1. Prescribed by an endocrinologist; and
2. One of the following:
    a. Clinical history of organic or idiopathic panhypopituitarism as a child; and
    b. History of idiopathic, isolated GH deficiency in childhood requiring documentation of GH response of less than 5 ng/ml to Insulin-induced hypoglycemia
3. For Genotropin®, Humatrope®, Saizen®, inadequate response or inability to tolerate ONE of the following:
    a. Norditropin®; or
    b. Nutropin®/Nutropin® AQ; or
    c. Omnitrope®

Initial authorization duration: 1 year

CONTINUATION CRITERIA Somatropin (Omnitrope®, Norditropin®, Genotropin®, Humatrope®, Saizen®, Nutropin® [AQ] is medically necessary when all of the following are met:

1. For Genotropin®, Humatrope®, Saizen® only, inadequate response or inability to tolerate ONE of the following:
    a. Nutropin®/Nutropin® AQ; or
    b. Norditropin®; or
    c. Omnitrope®; and
2. Yearly evaluation by an endocrinologist

Continuation authorization duration: 1 year

F. Dwarfism-Noonan syndrome

INITIAL CRITERIA Somatropin (Norditropin®) is medically necessary when ALL of the following are met:

1. Diagnosis of Noonan syndrome; and
2. Prescribed by an endocrinologist

Initial authorization duration: 1 year

CONTINUATION CRITERIA Somatropin (Norditropin®) is medically necessary when there is yearly evaluation by an endocrinologist
Continuation authorization duration: 1 year

G. Dwarfism short stature homeobox containing gene (SHOX) deficiency

INITIAL CRITERIA Somatropin (Humatrope® or Zomacton®) is medically necessary when ALL of the following are met:

1. Diagnosis of short stature or growth failure in children with short stature homeobox containing gene (SHOX) deficiency; and
2. Epiphyses are not closed; and
3. Prescribed by an endocrinologist

Initial authorization duration: 1 year

CONTINUATION CRITERIA Somatropin (Humatrope® or Zomacton®) is medically necessary when there is yearly evaluation by an endocrinologist
Continuation authorization duration: 1 year

H. Small for gestational age

INITIAL CRITERIA Somatropin (Humatrope®, Genotropin®, Norditropin®, Omnitrope®, or Zomacton®) is medically necessary when all of the following are met:

1. Failure to reach the third percentile for length/height by 2 years of age (Genotropin®, Omnitrope®) or 2 to 4 years of age (Norditropin®, Humatrope®); and
2. Prescribed by an endocrinologist; and
3. One of the following:
    a. Birth length and/or weight less than the third percentile for gestational age
    b. Birth weight less than 2500 grams and gestational age greater than 37 weeks
4. For Humatrope®, Genotropin®, and Zomacton® only, inadequate response or inability to tolerate ONE of the following:
    a. Norditropin®; or
    b. Omnitrope®

Initial authorization duration: 1 year

CONTINUATION CRITERIA Somatropin (Humatrope®, Genotropin®, Norditropin®, Omnitrope®, or Zomacton®) is medically necessary when all of the following are met:

1. Growth velocity greater than or equal to 2.5cm/year; and
2. For Humatrope®, Genotropin®, and Zomacton® only, inadequate response or inability to tolerate ONE of the following:
    a. Norditropin®; or
    b. Omnitrope: and
3. Yearly evaluation by an endocrinologist

Continuation authorization duration: 1 year

I. Hypopituitarism in childhood

INITIAL CRITERIA Somatropin (Omnitrope®, Norditropin®, Genotropin®, Humatrope®, Saizen®, Nutropin® [AQ] is medically necessary when all of the following are met:

1. Clinical evidence of a pituitary lesion or midline central nervous system defect; and

2. Prescribed by an endocrinologist; and
3. Growth velocity less than or equal to 5 cm/year after 2 years of age; and
4. Documentation of one of the following:
    a. Provocative testing, such as but not limited to the following:
        1. Levadopa
        2. Clonidine
        3. Insulin-induced hypoglycemia
    b. Deficiencies in two or more other hypothalamic-pituitary axes; and
5. For Genotropin®, Humatrope®, Saizen® only, inadequate response or inability to tolerate ONE of the following:
    a. Norditropin®; or
    b. Nutropin®/Nutropin AQ®; or
    c. Omnitrope®

Initial authorization duration: 1 year

CONTINUATION CRITERIA Somatropin (Omnitrope®, Norditropin®, Genotropin®, Humatrope®, Saizen®, Nutropin® [AQ] is medically necessary when all of the following are met:

1. For Genotropin®, Humatrope®, Saizen® only, inadequate response or inability to tolerate ONE of the following:
    a. Nutropin®/Nutropin AQ®; or
    b. Norditropin®; or
    c. Omnitrope®; and
2. Yearly evaluation by an endocrinologist

Continuation authorization duration: 1 year

J. Prader-Willi syndrome

INITIAL CRITERIA Somatropin (Omnitrope®, Genotropin®, or Norditropin®) is medically necessary when all of the following are met:

1. Diagnosis of Prader-Willi syndrome; and
2. Prescribed by an endocrinologist; and
3. For Genotropin® only, inadequate response or inability to tolerate ONE of the following:
    a. Norditropin®; or
    b. Omnitrope®

Initial authorization duration: 1 year

CONTINUATION CRITERIA Somatropin (Omnitrope®, Genotropin®, or Norditropin®) is medically necessary when BOTH of the following are met:

1. Yearly evaluation by an endocrinologist; and

2. For Genotropin® only, inadequate response or inability to tolerate ONE of the following:
    a. Norditropin®; or
    b. Omnitrope®

Continuation authorization duration: 1 year

K. Chronic Kidney Disease (CKD)

INITIAL CRITERIA Somatropin (Nutropin® [AQ]) is medically necessary when all of the following are met:

1. Diagnosis of growth failure associated with CKD; and
2. Height below the third percentile on standardized growth charts; and
3. Member is not a renal transplant recipient; and
4. Prescribed by an endocrinologist or nephrologist

Initial authorization duration: 1 year

CONTINUATION CRITERIA Somatropin (Nutropin® [AQ]) is medically necessary when all of the following are met:

1. No documentation of a renal transplant; and
2. Yearly evaluation by an endocrinologist or nephrologist; and
3. Growth velocity greater than or equal to 2 cm/year

Continuation authorization duration: 1 year

L. Short bowel syndrome

INITIAL CRITERIA Somatropin (Zorbtive®) is medically necessary when all of the following are met:

1. Diagnosis of short bowel syndrome; and

2. Member is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements); and
3. Member has not previously received 4 weeks of treatment with Zorbtive

Authorization duration: 6 weeks

M. AIDS wasting syndrome

INITIAL CRITERIA Somatropin (Serostim®) is medically necessary when all of the following are met:

1. Diagnosis of wasting (cachexia) associated with HIV; and
2. Concomitant antiretroviral therapy that has been optimized to decrease the viral load; and

3. Nutritional evaluation since onset of wasting first occurred

Initial authorization duration: 12 weeks

CONTINUATION CRITERIA Somatropin (Serostim®) is medically necessary when there is documentation of positive response to therapy (i.e., greater than or equal to 2% increase in body weight and/or body cell mass)
Continuation authorization duration: 36 weeks (for 48 weeks of total treatment)

P&T Approval Date: 11/2025

Title: Heart failure agents

Applicable Drugs:

Brand Name	Generic Name
Corlanor®	ivabradine
Verquvo™	vericiguat

Policy:

Chronic heart failure

INITAL CRITERIA: Corlanor® (ivabradine) is approved when ALL of the following are met:

1. Diagnosis of stable, symptomatic chronic heart failure; and
2. Member has New York Heart Association (NYHA) Class II, III, or IV symptoms; and
3. Member is 18 years of age or older; and
4. Left ventricular ejection fraction (LVEF) ≤ 35%; and
5. Sinus rhythm with resting heart rate ≥ 70 beats per minute; and
6. Member is clinically stable for at least 4 weeks on an optimized and stable clinical regimen which includes ALL of the following:
    a. Maximally tolerated doses of beta blockers (i.e., bisoprolol, carvedilol, metoprolol succinate ER) or inability to tolerate these beta blockers; and
    b. ACE inhibitors, ARBs or angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., Entresto) inability to tolerate ACE inhibitor or ARB or ARNI; and
    c. Sodium-glucose cotransporter-2 (SGLT-2) (e.g., Jardiance, Farxiga); and
    d. Mineralcorticoid receptor antagonist (MRA) (e.g., spironolactone, eplerenone); and
7. Prescribed by or in consultation with a cardiologist

INITIAL CRITERIA: Vericiguat (Verquvo™) is approved when ALL of the following are met:

1. Diagnosis of chronic heart failure; and
2. Member is age 18 or older; and
3. Member has an ejection fraction of less than 45 percent; and
4. Member has New York Heart Association (NYHA) Class II, III or IV symptoms; and
5. One of the following:
    1. Member was hospitalized for heart failure within the last 6 months; or
    2. Member used outpatient intravenous diuretics (e.g., bumetanide, furosemide) for heart failure within the last 3 months; and
6. Inadequate response or inability to tolerate ALL of the following at a maximally tolerated dose:
    1. One of the following:

        1. Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril); or
        2. Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan); or
        3. Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)]; and
    2. Beta blocker (i.e.., bisoprolol, carvedilol, metoprolol succinate ER; and
    3. Sodium-glucose cotransporter-2 (SGLT-2) inhibitors (e.g., Jardiance, Farxiga); and
    4. Mineralcorticoid receptor antagonist (MRA) (e.g., spironolactone, eplerenone); and
7. Prescribed by or in consultation with a cardiologist

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Vericiguat (Verquvo™) or ivabradine (Corlanor®) is re-approved when there is documentation of positive clinical response to therapy.
Reauthorization duration: 2 years

Inappropriate sinus tachycardia

INITIAL CRITERIA: Ivabradine (Corlanor®) is approved when ALL of the following are met:
1. Diagnosis of inappropriate sinus tachycardia confirmed by both of the following:
    1. Sinus heart rate greater than 100 beats per minute at rest; and
    2. Mean 24-hour heart rate greater than 90 beats per minute; and
2. Member is 18 years of age or older; and
3. Documentation that other causes of sinus tachycardia have been ruled out (e.g., hyperthyroidism, anemia, illicit stimulant drug use, caffeine, etc.); and
4. Inadequate response or inability to tolerate one beta-blocker; and-
5. Prescribed by or in consultation with a cardiologist

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Ivabradine (Corlanor®) is re-approved when there is documentation of positive clinical response to therapy.
Reauthorization duration: 2 years

Heart failure due to dilated cardiomyopathy

INITIAL CRITERIA: Ivabradine (Corlanor®) is approved when ALL of the following are met:
1. Diagnosis of stable, symptomatic heart failure due to dilated cardiomyopathy; and
2. Member has New York Heart Association (NYHA) Class II, III, or IV symptoms; and
3. Member is 6 months of age to 18 years of age; and
4. Member is in sinus rhythm; and
5. Member has elevated heart rate; and
6. Prescribed by or in consultation with a cardiologist; and

7. Inadequate response or inability to tolerate to one of the following:
    1. Beta blocker (e.g., bisoprolol, metoprolol succinate extended release)
    2. Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
    3. Diuretic Agent (e.g., spironolactone, furosemide)

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Ivabradine (Corlanor®) is re-approved when there is documentation of positive clinical response to therapy.
Reauthorization duration: 2 years

P&T Approval Date: 11/2025

HEPATITIS C TREATMENT

Preferred Agents, No Prior Authorization Required:
MAVYRET (Glecaprevir/Pibrentasvir)
SOFOSBUVIR/VELPATASVIR (Generic Epclusa)
LEDIPASVIR/SOFOSBUVIR (Generic Harvoni)

Non-Preferred Agents, Prior Authorization Required:
VOSEVI (sofosbuvir/ velpatasvir/voxilaprevir)
ZEPATIER (elbasvir/grazoprevir)
VIEKIRA PAK
SOVALDI (sofosbuvir)
HARVONI (ledipasvir/sofosbuvir)
PEG-INTRON/ PEGASYS (peginterferon alfa-2a)
RIBAVIRIN tablets or capsules
OR ANY OTHER NEWLY MARKETED AGENT for treatment of Hepatitis C

Where applicable and appropriate: MAVYRET (Glecaprevir/Pibrentasvir), SOFOSBUVIR/VELPATASVIR (GENERIC EPCLUSA), or LEDIPASVIR/SOFOSBUVIR (GENERIC HARVONI) are the PREFERRED AGENTS for Hepatitis C requests unless a documented medical reason has been provided (intolerance, hypersensitivity, contraindication, etc.) why the member is not able to use Mavyret, sofosbuvir/velpatasvir (generic Epclusa), or ledipasvir/sofosbuvir (generic Harvoni).

Initial requests must meet ALL of the following requirements:

1. Request must be for an appropriate FDA approved/AASLD guideline recommended indication, at an approved dose and duration, and for appropriate member (e.g. age/weight).
2. Member is 3 years of age or older
3. Provider attests that member does not have limited life expectancy of less than 12 months due to non-liver related comorbid conditions.
4. Provider attests that they have documentation of ALL the following:
    - A complete Hepatitis B immunization series OR Hepatitis B screening (sAb, sAg, and cAb)
    - Quantitative HBV DNA results if positive for hepatitis B sAg
    - If there is detectable HBV DNA, a treatment plan for Hepatitis B consistent with AASLD recommendations
    - If negative for Hepatitis B sAb, a hepatitis B immunization plan or counseling to receive the hepatitis B immunization series
5. Provider attests that they have documented HIV screening (HIV Ag/Ab), and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay, then one of the following:
    - Is being treated for HIV

- Is not being treated for HIV and the medical record documents the rationale for not being treated

6. Provider attests that all potential drug interactions with concomitant medications have been addressed (including discontinuation of the interacting drug, dose reduction, or counseling of the member of the risks associated with the use of both medications).
7. Provider attests if member is actively abusing alcohol or IV drugs, or has a history of abuse that they have counseled member regarding the risks of alcohol or IV drug abuse, and an offer of referral for substance abuse disorder treatment has been made.
8. Provider attests that member is committed to treatment plan, including lab monitoring and SVR12 lab testing will be completed and submitted to health plan.
9. The beneficiary has agreed to participate in Hepatitis C monitoring, educational and counseling program provided by the health plan
10. The request includes the completed DC Medicaid Beneficiary Disclosure and Commitment to Take Hepatitis C Medications Form
11. The following lab testing is required before treatment (copies of labs required)
    - Genotype (and subtype if provided) must be provided for:
        - Patients who are not going to receive Mavyret or generic Epclusa
        - Generic Epclusa in treatment naive patients with compensated cirrhosis
        - Patients who do not qualify for simplified treatment (treatment-experienced, have or had decompensated cirrhosis (Child-Pugh B and C), have ESRD, are HIV positive, have current HBV infection (positive for HbsAg), are pregnant, have known or suspected hepatocellular carcinoma, or have had a liver transplant)
    - Has documentation of AASLD-recommended resistance-associated substitution (RAS) testing:
        - Zepatier requests: all members with genotype 1a
        - Harvoni requests: treatment-experienced members with genotype 1a
        - Epclusa: treatment naïve members with cirrhosis and treatment experienced members without cirrhosis with genotype 3
12. All approvals are for 28 days supply (see treatment summary that follows), and will be consistent with labeling or current guidelines, and are subject to change as guidelines are updated.

TREATMENT SUMMARY

****For unique patient populations such as pediatric patients, please refer to bottom of the page for links to guideline specific treatment regimens****

For all charts, Epclusa and Harvoni refer to their generic formulations

Treatment Naïve			
Genotype	**Treatment Option**	**Duration**	
		No Cirrhosis	**Compensated Cirrhosis (Child-Pugh A)**

1, 2, 3, 4, 5, or 6	**Mavyret**	**8 weeks**	**8weeks**
1, 2, 3, 4, 5, or 6	**Epclusa**	**12 weeks**	**12 weeks**
1, 4, 5, or 6	**Harvoni**	**8-12 weeks^**	**12 weeks**

*Patients with genotype 3 who have compensated cirrhosis and are being prescribed Epclusa must be negative for the Y93H RAS to qualify for treatment

^Treatment-naive patients with genotype 1 and without cirrhosis who have HCV RNA <6 million units/mL and are HIV-uninfected may be considered for therapy of 8 weeks duration with Harvoni.

Treatment Experienced		Duration	
Failed Regimen	Treatment Options	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
Sofosbuvir-based (Sovaldi, Harvoni, and Epclusa) and Zepatier	Vosevi	12 weeks	12 weeksβ
	Mavyret*	16 weeks	16 weeks
Mavyret	Mavyret plus Sovaldi and ribavirin	16 weeks	16 weeks
	Vosevi	12 weeks	12 weeks^
Multiple including Vosevi or Sovaldi plus Mavyret	Mavyret plus Sovaldi and ribavirin	16 weeksμ	16 weeksμ
	Vosevi plus ribavirin	24 weeksμ	24 weeks

*Mavyret is an alternative regimen (Vosevi is preferred). Do not use for NS3/4 protease inhibitor inclusive therapies or genotype 3 infection with sofosbuvir/NS5A inhibitor experience.

βGenotype 3: If the patient has compensated cirrhosis, weight-based ribavirin is recommended.

^If the patient has compensated cirrhosis, weight-based ribavirin is recommended.

μMay be extended to 24 weeks in difficult cases (e.g. genotype 3 with cirrhosis) or failure following Sovaldi plus Mavyret

Unique patient populations (e.g. Decompensated Cirrhosis, Post-Transplant, etc. not addressed in previous tables)	
Decompensated Cirrhosis (Child-Pugh B or C)	Refer to current AASLD guidelines @ http://www.hcvguidelines.org/ **Note: If Mavyret, generic Epclusa, or generic Harvoni are a recommended treatment option in the guidelines, they are preferred** unless member has a trial and failure with a preferred product, or a documented medical reason has been provided (intolerance, hypersensitivity, contraindication, etc.) why the member is not able to use the preferred products.
Post-Transplant	
Hepatocellular Carcinoma	
Pediatrics	

Review/Revision Date: 11/2025

Prior Authorization Group Description	**Hypertrophic Cardiomyopathy**
Drugs	Formulary: Camzyos (mavacamten) Non-Formulary: Myqorzo (aficamten) Any other marketed agent within the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For reauthorization, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 05/2026
	<u>Initial Authorization:</u>
	• Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (oHCM)
	• Member has a left ventricular ejection fraction (LVEF) ≥55%
	• Member has a peak left ventricular outflow tract (LVOT) gradient ≥30 mmHg at rest or with provocation
	• Trial and failure or contraindication to ALL of the following:
	  o Beta blockers (i.e., metoprolol, propranolol, atenolol)
	  o Non-dihydropyridine calcium channel blockers (i.e., verapamil, diltiazem)
	• Prescriber attests that member is not diagnosed with a disorder that causes cardiac hypertrophy that mimics oHCM (i.e., Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy)
	• For Camzyos, prescriber attests that member is not using moderate to strong CYP2C19 inducers, strong CYP2C19 inhibitors, or moderate to strong CYP3A4 inducers
	• Medication is prescribed at an FDA approved dose
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary medications appropriate for the requested use (per the references outlined in "Covered Uses" or has a medical reason why these drug(s) cannot be used (e.g., intolerance, contraindication). For medications where there is only one formulary agent, only that agent must have been ineffective or not tolerated
	
	<u>Re-Authorization:</u>
	• Documentation of clinical benefit as evidenced by an improvement from baseline in oHCM symptoms (i.e., improvement in fatigue, chest pain, shortness of breath, LVOT, peak oxygen consumption, etc.) OR improvement or no worsening of NYHA functional class

	• Member has a left ventricular ejection fraction (LVEF) ≥50% for treatment with Camzyos OR ≥40% for treatment with Myqorzo • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Hypoactive Sexual Desire Disorder (HSDD) agents

Applicable Drugs:

Brand name	Generic name
Addyi®	Flibanserin
Vyleesi™	Bremelanotide

Policy:
INITIAL CRITERIA Flibanserin (Addyi®) is medically necessary when ALL of the following are met:

1. Diagnosis of one of the following:
    1. Acquired, generalized hypoactive sexual desire disorder (HSDD); or
    2. Female sexual interest/arousal disorder; and
2. Member is premenopausal; and
3. Symptoms of HSDD or female sexual interest/arousal disorder have persisted for at least 6 months; and
4. Member is 18 years of age or older; and
5. HSDD is not attributed to one of the following
    1. A co-existing medical or psychiatric condition
    2. Problems within a relationship
    3. Effects of a medication or other drug substance

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Flibanserin (Addyi®) is medically necessary when ALL of the following are met:

1. Positive clinical response to flibanserin (Addyi®) therapy; and
2. Member continues to be premenopausal

Reauthorization duration: 12 months

INITIAL CRITERIA Bremelanotide (Vyleesi™) is medically necessary when ALL of the following are met:

1. Diagnosis of one of the following:
    1. Acquired, generalized hypoactive sexual desire disorder (HSDD); or
    2. Female sexual interest/arousal disorder; and
2. Symptoms of HSDD or female sexual interest/arousal disorder have persisted for at least 6 months; and
3. Member is premenopausal; and
4. HSDD is not attributed to one of the following
    1. A co-existing medical or psychiatric condition
    2. Problems within a relationship
    3. Effects of a medication or other drug substance; and

5. Member does not have either of the following:
    1. Uncontrolled hypertension; or
    2. Known cardiovascular disease; and
6. Member is 18 years of age or older

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Bremelanotide (Vyleesi™) is medically necessary when ALL of the following are met:

1. Documentation of positive clinical response to Vyleesi™ therapy; and
2. Member continues to be premenopausal; and
3. Member does not have either of the following:
    1. Uncontrolled hypertension; or
    2. Known cardiovascular disease

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Title: Hypoxia-Inducible Factor Prolyl Hydroxylase (HIF-PH) Inhibitor

Applicable Drugs:

Brand Name	Generic Name
Vafseo®	Vadadustat

Policy:
INITIAL CRITERIA: Vadadustat (Vafseo®) is medically necessary when ALL of the following are met:

1. Documentation is provided of chronic kidney disease (CKD); and
2. Member is 18 years of age or older; and

3. Member has been on dialysis for at least 3 months and
4. Adequate iron stores confirmed by one of the following:
    a. Member's ferritin level is greater than 100 mcg/L; or
    b. Member's transferrin saturation (TSAT) is greater than 20%; and
5. Pretreatment hemoglobin level of less than 11 g/dL; and
6. Inadequate response to a minimum 12-week trial or inability to tolerate one of the following:
    1. Retacrit
    2. Procrit
    3. Aranesp; and

7. Prescribed by or in consultation with one of the following:
    a. Hematologist
    b. Nephrologist; and
8. Member is not on concurrent treatment with an erythropoietin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Vadadustat (Vafseo®) is medically necessary when ALL of the following are met:

1. Documentation is provided of a positive clinical response to therapy (e.g. increase in hemoglobin); and
2. Hemoglobin level does not exceed 12 g/dL; and
3. Adequate iron stores confirmed by one of the following:
    a. Member's ferritin level is greater than 100 mcg/L; or
    b. Member's transferrin saturation (TSAT) is greater than 20%; and

4. Member is not on concurrent treatment with an erythropoietin stimulating agents [ESA] (e.g., Aranesp, Epogen, Procrit)

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:
WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS.

- VAFSEO increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE).
- Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels.
- No trial has identified a hemoglobin target level, dose of VAFSEO, or dosing strategy that does not increase these risks.
- Use the lowest dose of VAFSEO sufficient to reduce the need for red blood cell transfusions.

P&T Approval Date: 11/2025

Title: Icosapent ethyl (Vascepa)

Applicable Drugs:

Brand name	Generic name
Vascepa®	Icosapent ethyl

Policy:

Severe Hypertriglyceridemia

INITIAL CRITERIA: Icosapent ethyl (Vascepa®) is approved when ALL of the following are met:

1. Diagnosis of severe hypertriglyceridemia defined as pre-treatment triglyceride level greater than or equal to 500 mg/dl; and
2. Member is 18 years of age or older; and
3. Medication will be used adjunct to an appropriate lipid-lowering diet; and
4. Member has an inadequate response or inability to tolerate omega-3-acid ethyl esters (generic Lovaza®); and
5. For Brand Vascepa® only, inadequate response or inability to tolerate generic Icosapent ethyl capsules

Initial authorization duration: 6 Months

REAUTHORIZATION CRITERIA: Icosapent ethyl (Vascepa®) is approved when ALL of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Member continues to use the medication adjunct to an appropriate lipid-lowering diet

Reauthorization duration: 2 years

Hypertriglyceridemia—Reduction of risk of cardiovascular events

INITIAL CRITERIA Icosapent ethyl (Vascepa®) is approved when ALL of the following are met:

1. Diagnosis of hypertriglyceridemia; and
2. Member is 18 years of age or older; and
3. Member has pre-treatment triglyceride level between 150 mg/dL to 499 mg/dL; and
4. ONE of the following:
    a. Member has established cardiovascular disease; or
    b. Both of the following:
        1. Diagnosis of diabetes mellitus; and

2. Member has 2 or more additional risk factors for cardiovascular disease (e.g., cigarette smoking, hypertension, creatinine clearance less than 60 ml/min, etc.); and

5. One of the following:
    a. Member has been receiving 12 consecutive weeks of statin therapy at maximally tolerated dose and will continue to receive statin therapy at maximally tolerated dose; or
    b. Inability to tolerate statin therapy; and
6. For Brand Vascepa® only, inadequate response or inability to tolerate generic Icosapent ethyl capsules

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Icosapent ethyl (Vascepa®) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy; and
2. One of the following:
    a. Member continues to receive statin therapy at maximally tolerated dose; or
    b. Inability to tolerate statin therapy

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Prior Authorization Group Description	**Imcivree (setmelanotide)**
Drugs	Imcivree (setmelanotide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Age appropriate per labeling
Prescriber Restrictions	Prescribed by or in consultation with medical geneticist, endocrinologist, or specialist in metabolic disorders
Coverage Duration	If the criteria are met, the request will be approved for 6 months, or 12 months for BBS.
Other Criteria	**Initial Authorization:** • Requested dose is appropriate per labeling • Documentation of current weight and body mass index (BMI) • BMI/weight must be one of the following: 1. BMI of 27 - 29.9 kg/m^2 with one of the following weight-related comorbidities: coronary artery disease, diabetes, hypertension, dyslipidemia, or obstructive sleep apnea 2. BMI of 30 kg/m^2 or more 3. For pediatric patients with: **- POMC, PCSK1, or LEPR Deficiency: weight must be ≥ 95th percentile for age on growth chart assessment** **- Bardet-Biedl syndrome: weight must be ≥ 97th percentile for age on growth chart assessment** • Documentation of counseling regarding lifestyle changes and behavioral modification (e.g. healthy diet and increased physical activity) • The patient meets one of the following: 1. Diagnosis of Bardet-Biedl syndrome (BBS) 2. Obesity is related to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency AND: a. Deficiency is documented by an FDA-approved genetic test confirming variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance b. POMC, PCSK1, or LEPR variants classified as benign or likely benign will not be approved

Revision/Review Date: 2/2026	**<u>Re-Authorization:</u>** • Documentation of at least 5% reduction in body weight compared with baseline or 5% of baseline BMI for patients with continued growth potential OR • For patients who had a baseline BMI of 27 - 29.9 kg/m2 with a weight-related comorbidity previously noted, an objective improvement is documented (e.g. reduction in blood pressure, cholesterol, hemoglobin A1c, etc). **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Immunoglobulin A (IgA) Nephropathy Agents**
Drugs	Fabhalta (iptacopan) Filspari (sparsentan) Tarpeyo (budesonide) Vanrafia (atrasentan) Voyxact (sibeprenlimab-szsi) Any other marketed agent within the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	For Filspari and Vanrafia only: • Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	If all of the criteria are met, the criteria will be approved as follows: Initial requests: • 6 months: Fabhalta • 9 months: Filspari, Tarpeyo, Vanrafia, Voyxact Reauthorization: • 12 months: Fabhalta, Filspari, Vanrafia, Voyxact • Reauthorization requests for Tarpeyo will not be allowed as the safety and efficacy of subsequent courses have not been established

Other Criteria	**<u>Initial Authorization:</u>**
	• Diagnosis of primary IgA nephropathy verified by biopsy
	• Member is on an ACE inhibitor or ARB at a maximally tolerated dose OR there is a medical reason that they cannot be on one
	• Member is on an SGLT2 inhibitor at a maximally tolerated dose OR there is a medical reason that they cannot be on one
	• Member has proteinuria (defined as total urine protein ≥0.5 g/day)
	• Member has an estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m^2
	• Medication is prescribed at an FDA approved dose
	• For Fabhalta:
	  o Documentation member complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria
	  o Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g

Review/Revision Date: 2/2026	○ Documentation of trial and failure, intolerance or contraindication to Filspari • For Filspari: ○ Documentation of baseline liver function ○ Attestation that member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, and/or aliskiren upon initiation of Filspari • For Vanrafia: ○ Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g ○ Documentation of trial and failure, intolerance or contraindication to Filspari • For Voyxact: ○ Documentation of trial and failure, intolerance or contraindication to Tarpeyo **Re-Authorization:** • Documentation of positive clinical response (e.g. decrease in UPCR, stabilization of eGFR) • Medication is prescribed at an FDA approved dose • For Filspari: ○ Documentation of liver function ***Reauthorization requests will not be allowed as the safety and efficacy of subsequent courses of Tarpeyo have not been established*** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Immune Modulating Therapies

Applicable Drugs:

Brand Name	Generic Name
Cimzia®	certolizumab
Cosentyx™	secukinumab
Enbrel®	etanercept
Kineret®	anakinra
Simponi®	golimumab
Orencia®	abatacept
Otezla®	apremilast
Xeljanz [XR]®	tofacitinib
Otrexup®, Rasuvo™, Reditrex	methotrexate
Taltz™	ixekizumab
Kevzara®	sarilumab
Siliq™	brodalumab
Tremfya®	guselkumab
Olumiant®	baricitinib
Arcalyst®	rilonacept
Skyrizi SQ	risankizumab-rzaa
Rinvoq, Rinvoq LQ	upadacitinib
Zeposia®	ozanimod
Adbry®	Tralokinumab-idrm
Cibinqo®	Abrocitinib
Sotyktu™	Deucravacitinib
Litfulo®	ritlecitinib
Bimzelx	bimekizumab-bkzx
Omvoh	mirikizumab-mrkz
Velsipity	etrasimod
Entyvio SQ	vedolizumab
Zymfentra	Infliximab-dyyb
Nemluvio	Nemolizumab-ilto

Ebglyss	Lebrikizumab-lbkz

Preferred Adalimumab Product(s)*[1]	**Non-preferred Adalimumab Product(s)**
Adalimumab-aacf (by Fresenius Kabi)	Adalimumab (Humira by Abbvie) Adalimumab (Humira by Cordavis)
Adalimumab-adbm (by Boehringer Ingelheim) 10mg/0.2ml and 20mg/0.4ml injections only	Adalimumab-atto (Amjevita™ by Amgen)
	Adalimumab-adbm (Cyltezo® by Boehringer Ingelheim) Adalimumab-adbm (by Boehringer Ingelheim, all strength and formulation except the preferred products listed)
	Adalimumab-adaz (Hyrimoz® by Sandoz) Adalimumab-adaz (by Sandoz) Adalimumab-adaz (Hyrimoz® by Cordavis)
	Adalimumab-aacf (Idacio® by Fresenius)
	Adalimumab-bwwd (Hadlima™ by Asmedsolut or Organon)
	Adalimumab-aqvh (Yusimry™ by Coherus Biosciences)
	Adalimumab-aaty (Yuflyma™ by Celltrion USA) Adalimumab-aaty (by Celltrion)
	Adalimumab-fkjp (Hulio® by Mylan Specialty L.P.) Adalimumab-fkjp (by Mylan Specialty L.P) Adalimumab-fkjp (by Biocon biologics) Adalimumab-fkjp (Hulio® by Biocon biologics)
	Adalimumab-afzb (Abrilada® by Pfizer U.S.)
	Adalimumab-ryvk (Simlandi® by Teva) Adalimumab-ryvk (by Quallent) Adalimumab-ryvk (by Quallent)

Preferred Ustekinumab Product(s)[2]	Non-preferred Ustekinumab Product(s)
Ustekinumab-kfce (Yesintek™ by Biocon Biologics)	Ustekinumab (Stelara® by Janssen Biotech)
	Ustekinumab-stba (Steqeyma® by Celltrion)
	Ustekinumab-aekn (Selarsdi™ by Teva)
	Ustekinumab-ttwe (Pyzchiva® by Sandoz)

Preferred Tocilizumab Product(s)[3]	Non-preferred Tocilizumab Product(s)
Tocilizumab-aazg (Tyenne® by Fresenius Kabi) Tocilizumab (Actemra® by Genentech)	tocilizumab-anoh (Avtozma)

Policy:

Adalimumab Products Non-preferred

Non-preferred adalimumab product(s)[1] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming ONE of the following diagnoses:
    1. moderate to severe rheumatoid arthritis
    2. moderate to severe polyarticular juvenile idiopathic arthritis (PJIA)
    3. active psoriatic arthritis
    4. moderate to severe chronic plaque psoriasis
    5. Ankylosing spondylitis
    6. moderate to severe Crohn's disease
    7. moderate to severe ulcerative colitis
    8. moderate to severe hidradenitis suppurative (i.e., Hurley stage II or III)
    9. non-infectious intermediate, posterior, or panuveitis; and
2. Submission of medical records (e.g., chart notes) confirming ONE of the following:
    1. BOTH of the following:
        1. Member has had an inadequate response to ONE preferred adalimumab product[1] for a period sufficient to determine clinical response as outlined in the clinical trial[4] for the indication requested; and
        2. Details on why the preferred adalimumab product[1] has not been effective is provided; or

2. BOTH of the following:
    1. Member has an inability to tolerate ONE preferred adalimumab product[1]; and
    2. Details of intolerability is provided; and
3. No concurrent therapy with any of other biologic DMARD (i.e., tumor necrosis factor antagonists); and
4. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Authorization duration: 12 months

Ustekinumab Products Non-preferred

Non-preferred ustekinumab product(s)[2] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming ONE of the following diagnoses:
    1. Active psoriatic arthritis
    2. Moderate to severe chronic plaque psoriasis
    3. Moderate to severe Crohn's disease
    4. Moderate to severe Ulcerative colitis; and
2. Submission of medical records (e.g., chart notes) confirming ONE of the following:
    1. BOTH of the following:
        1. Member has an inadequate response to ONE preferred ustekinumab product[2] for a period sufficient to determine clinical response as outlined in the clinical trial[4] for the indication requested; and
        2. Details on why the preferred ustekinumab product[2] has not been effective is provided; or
    2. BOTH of the following:
        1. Member has an inability to tolerate ONE preferred ustekinumab product[2]; and
        2. Details of intolerability is provided; and
3. No concurrent therapy with any of other biologic DMARD (i.e., tumor necrosis factor antagonists); and
4. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Authorization duration: 12 months

Tocilizumab Products Non-preferred

Non-preferred tocilizumab product(s)[3] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis
    2. Moderate to severe polyarticular juvenile idiopathic arthritis
    3. Giant cell arteritis
    4. Active systemic juvenile idiopathic arthritis
    5. Systemic sclerosis-associated interstitial lung disease; and
2. Submission of medical records (e.g., chart notes) confirming ONE of the following:
    1. BOTH of the following:
        1. Member has an inadequate response to ONE preferred tocilizumab product[3] for a period sufficient to determine clinical response as outlined in the clinical trial[4] for the indication requested; and
        2. Details on why the preferred tocilizumab product[3] has not been effective is provided; or
    2. BOTH of the following:
        1. Member has an inability to tolerate ONE preferred tocilizumab product[3]; and
        2. Details of intolerability is provided; and
3. No concurrent therapy with any of other biologic DMARD (i.e., tumor necrosis factor antagonists); and
4. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Authorization duration: 12 months

4. Clinical trial supporting indication approval as described in the drug Prescribing Information, or in accordance with criteria outlined in the Off-Label Use policy.

Rheumatoid Arthritis (RA)

INITIAL CRITERIA Preferred adalimumab product[1] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 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 that the member had inadequate response of inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Certolizumab (Cimzia®), golimumab (Simponi®), etanercept (Enbrel®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 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 that the member had inadequate response of inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Tofacitinib (Xeljanz [XR]® tablets/extended-release tablets) or upadacitinib (Rinvoq™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 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 that the member had inadequate response of inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Anakinra (Kineret®), sarilumab (Kevzara®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 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 that the member had inadequate response of inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. ONE of the following:
    1. Both of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
            1. One preferred adalimumab product[1]
            2. certolizumab (Cimzia®)
            3. golimumab (Simponi®)

4. etanercept (Enbrel®)
5. tofacitinib (Xeljanz [XR]® tablets/extended-release tablets)
6. upadacitinib (Rinvoq®); and

2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH of the following: abatacept (Orencia® SQ) and preferred tocilizumab product[3]; or

2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and

6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Baricitinib (Olumiant®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 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 that the member had inadequate response of inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. ONE of the following:
    1. Both of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
            1. One preferred adalimumab product[1]
            2. certolizumab (Cimzia®)
            3. golimumab (Simponi®)
            4. etanercept (Enbrel®)
            5. tofacitinib (Xeljanz [XR]® tablets/extended-release tablets)
            6. upadacitinib (Rinvoq™); and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH of the following: abatacept (Orencia® SQ) and preferred tocilizumab product; or
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Abatacept (Orencia® SQ) or preferred tocilizumab product[3] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 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 that the member had an inadequate response or inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. One of the following:
    1. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
        1. One preferred adalimumab product[1]
        2. certolizumab (Cimzia®)
        3. golimumab (Simponi®)
        4. etanercept (Enbrel®)
        5. tofacitinib (Xeljanz [XR]® tablets/extended-release tablets)
        6. upadacitinib (Rinvoq®); or
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of severe, active rheumatoid arthritis (RA); and
2. Prescribed by or in consultation with a rheumatologist; and
3. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate oral methotrexate; and
4. For Otrexup™ and Reditrex™ only: paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate Rasuvo®; and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Preferred adalimumab product[1], certolizumab (Cimzia®), golimumab (Simponi®), tofacitinib (Xeljanz [XR]® tablets/extended-release tablets), upadacitinib (Rinvoq™), anakinra (Kineret®), etanercept (Enbrel®), sarilumab (Kevzara®), baricitinib (Olumiant®), abatacept (Orencia® SQ), preferred tocilizumab product[3] or methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Reduction in total active (swollen and tender) joint count from baseline; or
    b. Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline; and
2. ONE of the following:

a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or

b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Ankylosing Spondylitis (AS)

INITIAL CRITERIA: Preferred adalimumab product[1] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of ankylosing spondylitis (AS); and
2. Member is 18 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 that the member had an inadequate response or inability to tolerate two different NSAIDS at maximally tolerated doses; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Certolizumab (Cimzia®), etanercept (Enbrel®), or golimumab (Simponi®), Ixekizumab (Taltz®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of ankylosing spondylitis (AS); and
2. Member is 18 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 that the member had an inadequate response or inability to tolerate two different NSAIDS at maximally tolerated doses; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Secukinumab (Cosentyx®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active ankylosing spondylitis (AS); and
2. Member is 18 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 that the member had inadequate response or inability to tolerate two different NSAIDS at maximally tolerated doses; and
5. One of the following:
    1. Both of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate TWO of the following:
            1. One preferred adalimumab product[1]
            2. certolizumab (Cimzia®)
            3. golimumab (Simponi®)

4. etanercept (Enbrel®)
5. tofacitinib (Xeljanz [XR]® tablets/extended-release tablets)
6. upadacitinib (Rinvoq™); and

2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH ixekizumab (Taltz®) and bimekizumab (Bimzelx) or

2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and

6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Bimekizumab (Bimzelx®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active ankylosing spondylitis (AS); and
2. Member is 18 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 that the member had inadequate response or inability to tolerate two different NSAIDS at maximally tolerated doses; and
5. One of the following:
    1. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate TWO of the following:
        1. One preferred adalimumab product[1]
        2. certolizumab (Cimzia®)
        3. golimumab (Simponi®)
        4. etanercept (Enbrel®)
        5. tofacitinib (Xeljanz [XR]® tablets/extended-release tablets)
        6. upadacitinib (Rinvoq™)
        7. ixekizumab (Taltz®); and
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Tofacitinib (Xeljanz [XR]® tablets/extended-release tablets) or upadacitinib (Rinvoq®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active ankylosing spondylitis (AS); and
2. Member is 18 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 that the member had an inadequate response or inability to tolerate two different NSAIDS at maximally tolerated doses; and

5. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or intolerance to one of more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab); and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Preferred adalimumab product[1], certolizumab (Cimzia®), golimumab (Simponi®), Etanercept (Enbrel®), secukinumab (Cosentyx®), tofacitinib (Xeljanz [XR]® tablets/extended-release tablets), ixekizumab (Taltz®), upadacitinib (Rinvoq®), or bimekizumab (Bimzelx®) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidence by improvement from baseline by at least one of the following:
    a. Disease activity (e.g., pain, fatigue, inflammation, stiffness); or
    b. Lab values (erythrocyte sedimentation rate, C-reactive protein level); or
    c. Axial status (e.g., lumbar spine motion, chest expansion); or
    d. Total active (swollen or tender) joint count; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Polyarticular Juvenile Idiopathic Arthritis

INITIAL CRITERIA: Preferred adalimumab product[1] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA); and
2. Member is 2 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 that the member had an inadequate response or inability to tolerate ONE of the following DMARDs at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Etanercept (Enbrel®), certolizumab pegol (Cimzia®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA); and
2. Member is 2 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 that the member had an inadequate response or inability to tolerate ONE of the following DMARDs at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and

5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Sarilumab (Kevzara®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA); and
2. Member weighs at least 63 kg; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate ONE of the following DMARDs at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. One of the following:
    1. Both of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
            1. One preferred adalimumab product[1]
            2. tofacitinib (Xeljanz® tablets and oral solution)
            3. etanercept (Enbrel®)
            4. upadacitinib (Rinvoq/Rinvoq LQ®)
            5. certolizumab pegol (Cimzia®); and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH of the following:
            1. Preferred tocilizumab product[3]; and
            2. Abatacept (Orencia®); or
    2. Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: preferred tocilizumab product[3] abatacept (Orencia® SQ) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA); and
2. Member is 2 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 that the member had an inadequate response or inability to tolerate ONE of the following DMARDs at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
        1. One preferred adalimumab product[1]
        2. tofacitinib (Xeljanz® tablets and oral solution)
        3. etanercept (Enbrel®)
        4. Upadacitinib (Rinvoq®/Rinvoq LQ)
        5. Certolizumab pegol (Cimzia®); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Tofacitinib (Xeljanz® tablets and oral solution), Upadacitinib (Rinvoq®, Rinvoq LQ®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA); and
2. Member is 2 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 that the member had an inadequate response or inability to tolerate ONE of the following DMARDs at maximally tolerated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Member had an inadequate response or inability to tolerate one or more TNF inhibitors (e.g., adalimumab, etanercept, certolizumab pegol); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA); and
2. Prescribed by or in consultation with a rheumatologist; and
3. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate oral methotrexate; and

4. For Otrexup™ and Reditrex™ only: paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate Rasuvo®; and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Preferred adalimumab product[1], preferred tocilizumab product[3], abatacept (Orencia® SQ), tofacitinib (Xeljanz® tablets and oral solution), Upadacitinib (Rinvoq®, Rinvoq LQ®), etanercept (Enbrel®), Sarilumab (Kevzara®), certolizumab pegol (Cimzia®) or methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Reduction in the total active (swollen and tender) joint count from baseline; or
    b. Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Psoriatic Arthritis

INITIAL CRITERIA: Preferred adalimumab product[1] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Certolizumab (Cimzia®), apremilast (Otezla®), golimumab (Simponi®), guselkumab (Tremfya®), ixekizumab (Taltz®) or risankizumab (Skyrizi® SQ), is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Etanercept (Enbrel®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 2 years of age or older; and

3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Preferred ustekinumab product[2] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 6 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Upadacitinib (Rinvoq®, Rinvoq LQ®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 2 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Abatacept (Orencia® SQ) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 2 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. One of the following:

1. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or inability to tolerate TWO of the following:
    1. One preferred adalimumab product[1]
    2. certolizumab (Cimzia®)
    3. One preferred ustekinumab product[2]
    4. golimumab (Simponi®)
    5. etanercept (Enbrel®)
    6. guselkumab (Tremfya®)
    7. risankizumab (Skyrizi™)
    8. tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets)
    9. upadacitinib (Rinvoq/Rinvoq LQ®)
    10. ixekizumab (Taltz®); or
2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and

5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Secukinumab (Cosentyx®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 2 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. One of the following:
    1. All of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or inability to tolerate TWO of the following:
            1. One preferred adalimumab product[1]
            2. certolizumab (Cimzia®)
            3. golimumab (Simponi®)
            4. One preferred ustekinumab product[2]
            5. etanercept (Enbrel®)
            6. guselkumab (Tremfya®)
            7. risankizumab (Skyrizi™)
            8. tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets)
            9. upadacitinib (Rinvoq/Rinvoq LQ®); and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or inability to tolerate BOTH of the following: ixekizumab (Taltz®) AND abatacept (Orencia® SQ) or bimekizumab (Bimzelx®); or
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and

5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Bimekizumab (Bimzelx®) is medically necessary when ALL of the following are met:
1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. One of the following:
    1. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or inability to tolerate TWO of the following:
        1. One preferred adalimumab product[1]
        2. certolizumab (Cimzia®)
        3. golimumab (Simponi®)
        4. One preferred ustekinumab product[2]
        5. etanercept (Enbrel®)
        6. guselkumab (Tremfya®)
        7. risankizumab (Skyrizi™)
        8. tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets)
        9. upadacitinib (Rinvoq/Rinvoq LQ®)
        10. ixekizumab (Taltz®); and
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Methotrexate injection (i.e., Otrexup®, Rasuvo®, Reditrex™) is medically necessary when ALL of the following are met:
1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of psoriatic arthritis (PsA); and
2. Prescribed by or in consultation with a rheumatologist or dermatologist; and
3. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate oral methotrexate; and
4. For Otrexup™ and Reditrex™ only: Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate Rasuvo®; and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Preferred adalimumab product*[1], certolizumab (Cimzia®), preferred ustekinumab product[2], apremilast (Otezla®), golimumab (Simponi®), guselkumab (Tremfya®), abatacept (Orencia® SQ), tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets), Ixekizumab (Taltz®), etanercept (Enbrel®), secukinumab (Cosentyx®), methotrexate injection (i.e., Otrexup®, Rasuvo®,

Reditrex™), upadacitinib (Rinvoq™®, Rinvoq LQ®), risankizumab (Skyrizi® SQ), or bimekizumab (Bimzelx®) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Reduction in the total active (swollen and tender) joint count from baseline; or
    b. Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline; or
    c. Reduction in the body surface area involvement from baseline; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved
    Reauthorization duration: 12 months

Plaque Psoriasis

INITIAL CRITERIA: Preferred adalimumab product[1] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic®), topical retinoids; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Guselkumab (Tremfya®), certolizumab (Cimzia®), deucravacitinib (Sotyktu™) or risankizumab (Skyrizi® SQ) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic®), topical retinoids; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Apremilast (Otezla®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of plaque psoriasis; and
2. Both of the following:
    a. Member is 6 years of age or older; and

b. Member weighs at least 20 kg; and

3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic®), topical retinoids; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Preferred ustekinumab product[2] or ixekizumab (Taltz™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 6 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic®), topical retinoids; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Secukinumab (Cosentyx™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 6 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and

4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic), topical retinoids; and
5. One of the following:
    1. BOTH of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
            1. certolizumab (Cimzia®)
            2. One preferred adalimumab product[1]
            3. One preferred ustekinumab product[2]
            4. etanercept (Enbrel®)
            5. guselkumab (Tremfya®)
            6. risankizumab (Skyrizi™)
            7. apremilast (Otezla®)
            8. deucravacitinib (Sotyktu®); and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH ixekizumab (Taltz®) and bimekizumab (Bimzelx®); or
    2. BOTH of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH ixekizumab (Taltz®) and bimekizumab (Bimzelx®); and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Etanercept (Enbrel®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 4 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic), topical retinoids; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of severe psoriasis; and

2. Member is age 18 years or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response to ALL other standard therapy (e.g., oral methotrexate, all topical therapy modalities, phototherapy, etc.); and
5. For Otrexup™ and Reditrex™ only: Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate Rasuvo®; and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Bimekizumab (Bimzelx®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic), topical retinoids; and
5. One of the following:
    1. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
        1. certolizumab (Cimzia®),
        2. One preferred adalimumab product[1]
        3. One preferred ustekinumab product[2]
        4. etanercept (Enbrel®)
        5. guselkumab (Tremfya®)
        6. risankizumab (Skyrizi™)
        7. apremilast (Otezla®)
        8. ixekizumab (Taltz®)
        9. deucravacitinib (Sotyktu®); and
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Preferred adalimumab product[1], guselkumab (Tremfya®), certolizumab (Cimzia®), risankizumab (Skyrizi® SQ), apremilast (Otezla®), Preferred ustekinumab product[2], secukinumab (Cosentyx™), ixekizumab (Taltz™), etanercept (Enbrel®), deucravacitinib (Sotyktu™), bimekizumab (Bimzelx®) or methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is medically necessary when ALL of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by one of the following:
    a. Reduction in body surface area (BSA) involvement from baseline; or

b. Improvement in symptoms (e.g., pruritus, inflammation) from baseline; and

2. For secukinumab (Cosentyx) only, paid claim or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH ixekizumab (Taltz) and bimekizumab (Bimzelx®); and
3. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

INITIAL CRITERIA Brodalumab (Siliq™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic®), topical retinoids; and
5. One of the following:
    1. BOTH of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
            1. One preferred adalimumab product[1]
            2. One preferred ustekinumab product[2]
            3. certolizumab (Cimzia®
            4. etanercept (Enbrel®)
            5. risankizumab (Skyrizi)
            6. guselkumab (Tremfya®)
            7. apremilast (Otezla®)
            8. deucravacitinib (Sotyktu®); and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH bimekizumab (Bimzelx) and ixekizumab (Taltz®); or
    2. BOTH of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH bimekizumab (Bimzelx) and ixekizumab (Taltz®); and
6. Member has been evaluated for depression and suicidal ideations using the Patient Health Questionnaire (PHQ)-9; and
7. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 16 weeks

REAUTHORIZATION CRITERIA Brodalumab (Siliq™) is medically necessary when ALL of the following are met:

1. Member has positive response to therapy with brodalumab (Siliq®) as evidenced by one of the following:
    a. Reduction of the body surface area (BSA) involvement from baseline; or
    b. Improvement in symptoms (e.g., pruritus, inflammation) from baseline; and
2. Paid claim or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate bimekizumab (Bimzelx) and ixekizumab (Taltz); and
3. Member has been evaluated for depression and suicidal ideations using the Patient Health Questionnaire (PHQ)-9; and
4. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Crohn's Disease

INITIAL CRITERIA: Preferred adalimumab product[1] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe Crohn's disease; and
2. Member is 6 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate one drug from any of TWO of the following groups:
    a. Corticosteroids: budesonide (Entocort® EC), prednisone, hydrocortisone, methylprednisolone; or
    b. Aminosalicylates: sulfasalazine, mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®); or
    c. Immunomodulators: azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus (Prograf®), methotrexate; or
6. Antibiotics: metronidazole, levofloxacin; andDosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Certolizumab (Cimzia®), Preferred ustekinumab product2, guselkumab (Tremfya® SQ), mirikizumab (Omvoh® SQ) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe Crohn's disease; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate one drug from any of TWO of the following groups:
    a. Corticosteroids: budesonide (Entocort® EC), prednisone, hydrocortisone, methylprednisolone; or
    b. Aminosalicylates: sulfasalazine, mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®); or
    c. Immunomodulators: azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus (Prograf®), methotrexate; or
    d. Antibiotics: metronidazole, levofloxacin; and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Risankizumab (Skyrizi® SQ) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe Crohn's disease; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Paid claims or submission of medical records (e.g., chart notes) confirming ONE of the following:
    1. Member had inadequate response or inability to tolerate one drug from any of TWO of the following groups:

1. Corticosteroids: budesonide (Entocort® EC), prednisone, hydrocortisone, methylprednisolone; or
2. Aminosalicylates: sulfasalazine, mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®); or
3. Immunomodulators: azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus (Prograf®), methotrexate; or
4. Antibiotics: metronidazole, levofloxacin; or

2. Risankizumab (Skyrizi® SQ) will be used as a maintenance dose following the intravenous induction doses; and

6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Upadacitinib (Rinvoq®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe Crohn's disease; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate one drug from any of TWO of the following groups:
   a. Corticosteroids: budesonide (Entocort® EC), prednisone, hydrocortisone, methylprednisolone; or
   b. Aminosalicylates: sulfasalazine, mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®); or
   c. Immunomodulators: azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus (Prograf®), methotrexate; or
   d. Antibiotics: metronidazole, levofloxacin; and
6. Member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, golimumab); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe Crohn's disease; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. For Otrexup™ and Reditrex™ only: Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate Rasuvo®; and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Infliximab (Zymfentra™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderately to severely active Crohn's disease; and
2. Member is 18 years of age or older; and
3. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and

4. ONE of the following:
    1. BOTH of the following:
        1. Paid claims of submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate one drug from any of TWO of the following groups:
            1. Corticosteroids: budesonide (Entocort® EC), prednisone, hydrocortisone, methylprednisolone; or
            2. Aminosalicylates: sulfasalazine, mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®); or
            3. Immunomodulators: azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus (Prograf®), methotrexate; or
            4. Antibiotics: metronidazole, levofloxacin; and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate TWO of the following:
            1. One preferred adalimumab product[1]
            2. Certolizumab (Cimzia®)
            3. Risankizumab (Skyrizi®)
            4. Upadacitinib (Rinvoq®)
            5. One preferred ustekinumab product[2]; or
    2. Submission of medical records (e.g., chart notes) confirming that the member has achieved a clinical response following a minimum of 10 weeks of IV infliximab; and
5. Prescribed by or in consultation with a gastroenterologist; and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Vedolizumab (Entyvio®) SQ is medically necessary when ALL of the following are met:
1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderately to severely active Crohn's disease; and
2. Member is 18 years of age or older; and
3. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
4. ONE of the following:
    1. BOTH of the following:
        1. Paid claims of submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate one drug from any of TWO of the following groups:
            1. Corticosteroids: budesonide (Entocort® EC), prednisone, hydrocortisone, methylprednisolone; or
            2. Aminosalicylates: sulfasalazine, mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®); or
            3. Immunomodulators: azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus (Prograf®), methotrexate; or
            4. Antibiotics: metronidazole, levofloxacin; and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate TWO of the following:

1. One preferred adalimumab product[1]
2. Certolizumab (Cimzia®)
3. Risankizumab (Skyrizi®)
4. One preferred ustekinumab product[2]
5. Upadacitinib (Rinvoq®); or

2. Paid claims or submission of medical records (e.g., chart notes) confirming ONE of the following:
    1. Will be used as maintenance dose following two doses of Entyvio IV for induction; or
    2. Member is currently established on Entyvio IV; and
5. Prescribed by or in consultation with a gastroenterologist; and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Preferred adalimumab product1, certolizumab (Cimzia®), Preferred ustekinumab product2, risankizumab (Skyrizi® SQ), infliximab (Zymfentra™), vedolizumab (Entyvio®), methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™), upadacitinib (Rinvoq®), guselkumab (Tremfya® SQ), mirikizumab (Omvoh® SQ) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following:
    a. Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline; or
    b. Reversal of high fecal output state; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Ulcerative Colitis

INITIAL CRITERIA: One preferred ustekinumab product[2] or golimumab (Simponi®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe ulcerative colitis (UC); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Risankizumab (Skyrizi® SQ), guselkumab (Tremfya® SQ), mirikizumab (Omvoh® SQ) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate

to severe ulcerative colitis (UC); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming ONE of the following:
    a. member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; or
    b. Risankizumab-rzaa (Skyrizi® SQ), guselkumab (Tremfya® SQ), mirikizumab (Omvoh® SQ) will be used as a maintenance dose following the intravenous induction doses; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Preferred adalimumab product[1] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe ulcerative colitis (UC); and
2. Member is 5 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Ozanimod (Zeposia®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe ulcerative colitis (UC); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
5. One of the following:
    1. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
        1. One preferred adalimumab product[1]
        2. One preferred ustekinumab product[2]
        3. golimumab (Simponi®)
        4. upadacitinib (Rinvoq®)
        5. Risankizumab (Skyrizi®)
        6. tofacitinib (Xeljanz®/Xeljanz® XR)
        7. guselkumab (Tremfya® SQ)
        8. Mirikizumab (Omvoh® SQ); or
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day

gap in therapy; and

6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Etrasimod (Velsipity™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe ulcerative colitis (UC); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
5. One of the following:
    1. BOTH of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
            1. One preferred adalimumab product[1]
            2. One preferred ustekinumab product[2]
            3. golimumab (Simponi®)
            4. upadacitinib (Rinvoq®)
            5. Risankizumab (Skyrizi®)
            6. tofacitinib (Xeljanz®/Xeljanz® XR)
            7. guselkumab (Tremfya®)
            8. Mirikizumab (Omvoh® SQ); and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ozanimod (Zeposia®); or
    2. BOTH of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
        2. Documentation of positive clinical response to therapy as evidenced by ONE of the following:
            1. Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline; or
            2. Reversal of high fecal output state; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets), or upadacitinib (Rinvoq®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe ulcerative colitis (UC); and
2. Member is 18 years of age or older; and

3. Prescribed by or in consultation with a gastroenterologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
5. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of more TNF inhibitors (e.g., adalimumab, golimumab); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Vedolizumab (Entyvio®) SQ is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe Ulcerative colitis (UC); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. ONE of the following:
    1. BOTH of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate TWO of the following:
            1. One preferred adalimumab product[1]
            2. One preferred ustekinumab product[2]
            3. Golimumab (Simponi®)
            4. Upadacitinib (Rinvoq®)
            5. Risankizumab (Skyrizi®)
            6. Tofacitinib (Xeljanz®/Xeljanz® XR)
            7. Guselkumab (Tremfya® SQ)
            8. Mirikizumab (Omvoh® SQ); or
    2. Paid claims or submission of medical records (e.g., chart notes) confirming ONE of the following:
        1. Will be used as a maintenance dose following two doses of Entyvio IV for induction; or
        2. Member is currently established on Entyvio IV; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Infliximab (Zymfentra™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of

moderately to severely active ulcerative colitis; and

2. Member is 18 years of age or older; and
3. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
4. ONE of the following:
    1. BOTH of the following:
        1. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
        2. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate TWO of the following:
            1. One preferred adalimumab product[1]
            2. One preferred ustekinumab product[2]
            3. Golimumab (Simponi®)
            4. Upadacitinib (Rinvoq®)
            5. Risankizumab (Skyrizi®)
            6. Tofacitinib (Xeljanz®/Xeljanz® XR)
            7. Guselkumab (Tremfya® SQ)
            8. Mirikizumab (Omvoh® SQ); or
    2. Submission of medical records (e.g., chart notes) confirming that the member has achieved a clinical response to therapy following a minimum of 10 weeks of IV infliximab; and
5. Prescribed by or in consultation with a gastroenterologist; and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Preferred adalimumab product***[1]**, Preferred ustekinumab product[2], golimumab (Simponi®), tofacitinib (Xeljanz® /Xeljanz® XR tablets/extended-release tablets), upadacitinib (Rinvoq®), ozanimod (Zeposia®), mirikizumab (Omvoh™), etrasimod (Velsipity™), vedolizumab (Entyvio®)SQ, infliximab (Zymfentra™), Risankizumab (Skyrizi® SQ), guselkumab (Tremfya® SQ) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Improvement in intestinal inflammation (e.g., mucosal healing, improvement in lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline; or
    b. Reversal of high fecal output state; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Cryopyrin-Associated Periodic Syndromes

INITIAL CRITERIA: Anakinra (Kineret®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of Neonatal-

Onset Multisystem Inflammatory Disease (NOMID); and
2. Prescribed by or in consultation with a rheumatologist or other appropriate specialist; and
3. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
4. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Anakinra (Kineret®) is medically necessary when BOTH of the following are met:
1. Documentation of positive clinical response to therapy; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

INITIAL CRITERIA: Rilonacept (Arcalyst®) is medically necessary when there ALL of the following are met:
1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of Cryopyrin-Associated Periodic Syndromes including Familial cold Auto-Inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS); and
2. Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist, or other medical specialist; and
3. Member is 12 years of age or older; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA rilonacept (Arcalyst®) is medically necessary when BOTH of the following are met:
1. There is documentation of positive clinical response to therapy as evidenced by one of the following:
    a. Improvement in rash, fever, joint pain, headache, or conjunctivitis; or
    b. Decreased number of disease flare days; or
    c. Normalization of inflammatory markers (C-reactive protein [CRP], erythrocyte sedimentation rate [ESR], serum amyloid A [SAA]); or
    d. Corticosteroid dose reduction; or
    e. Improvement in MD global score or active joint count; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Hidradenitis Suppurativa

INITIAL CRITERIA: Preferred adalimumab product[1] is medically necessary when ALL of the following are

met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a 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. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
4. Member is 12 years of age or older; and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: bimekizumab-bkzx (Bimzelx®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley stage II or III); and
2. Member is 18 years of age or older; and
3. One of the following:
    1. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate ONE preferred adalimumab product[1]; or
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than 45 days gap in therapy; and
4. Prescribed by or in consultation with a dermatologist; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Secukinumab (Cosentyx®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley stage II or III); and
2. Member is 18 years of age or older; and
3. One of the following:
    1. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate TWO of the following:
        1. One preferred adalimumab product[1]; and
        2. Bimekizumab-bkzx (Bimzelx®); or
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and
4. Prescribed by or in consultation with a dermatologist; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Preferred adalimumab product[1], bimekizumab-bkzx (Bimzelx®), Secukinumab (Cosentyx®) is medically necessary when BOTH of the following are met

1. There is documentation of positive clinical response to therapy; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Uveitis

INITIAL CRITERIA: Preferred adalimumab product[1] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of non-infectious intermediate, posterior, or panuveitis; and
2. Prescribed by or in consultation with an ophthalmologist or rheumatologist; and
3. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ophthalmic and oral corticosteroids; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Member is 2 years of age or older; and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Preferred adalimumab product[1] is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Giant Cell Arteritis

INITIAL CRITERIA: upadacitinib (Rinvoq), preferred tocilizumab product3 medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of Giant Cell Arteritis; and
2. Prescribed by or in consultation with a rheumatologist; and
3. Member is 18 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate a glucocorticoid (i.e., prednisone); and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: upadacitinib (Rinvoq), preferred tocilizumab product3 is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. ONE of the following:

a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

DRUG	DOSE
Upadacitinib (Rinvoq)	15mg once daily
Tocilizumab (Actemra® SQ) and its biosimilars	162 mg given once every week

Systemic Juvenile Idiopathic Arthritis

INITIAL CRITERIA: preferred tocilizumab product[3] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active systemic juvenile idiopathic arthritis (SIJA); and
2. Prescribed by or in consultation with a rheumatologist; and
3. Member is 2 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following conventional therapies at maximally tolerated doses:
    a. Non-steroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen); or
    b. Systemic glucocorticoid (e.g., prednisone)
    c. DMARDs (e.g., leflunomide, methotrexate); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Preferred tocilizumab product[3] is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Reduction in the total active (swollen and tender) joint count from baseline; or
    b. Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Non-radiographic axial spondyloarthritis (nr-axSpA)

INITIAL CRITERIA: Certolizumab (Cimzia®), Ixekizumab (Taltz®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacrolitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on

sacroiliac joints); and
3. Member is 18 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate two different NSAIDs (e.g., diclofenac, meloxicam, naproxen) at maximally tolerated doses; and
5. Prescribed by or in consultation with a rheumatologist; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Upadacitinib (Rinvoq™) is medically necessary when ALL of the following are met:
1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacrolitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints); and
3. Member is 18 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate two different NSAIDs (e.g., diclofenac, meloxicam, naproxen) at maximally tolerated doses; and
5. Prescribed by or in consultation with a rheumatologist; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., certolizumab pegol); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Secukinumab (Cosentyx®) is medically necessary when ALL of the following are met:
1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacrolitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints); and
3. Member is 18 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate two different NSAIDs (e.g., diclofenac, meloxicam, naproxen) at maximally tolerated doses; and
5. Prescribed by or in consultation with a rheumatologist; and
6. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ALL of the following: certolizumab (Cimzia®), Upadacitinib (Rinvoq™), Ixekizumab (Taltz®), and bimekizumab (Bimzelx®); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than a 45-day gap in therapy; and

7. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Bimekizumab (Bimzelx®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacrolitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints); and
3. Member is 18 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate two different NSAIDs (e.g., diclofenac, meloxicam, naproxen) at maximally tolerated doses; and
5. Prescribed by or in consultation with a rheumatologist; and
6. One of the following:
    1. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
        1. certolizumab (Cimzia®),
        2. Upadacitinib (Rinvoq™),
        3. Ixekizumab (Taltz®); or
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product, defined as no more than 45-day gap in therapy; and
7. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Certolizumab (Cimzia®), upadacitinib (Rinvoq™), ixekizumab (Taltz®), secukinumab (Cosentyx®) or Bimekizumab (Bimzelx®) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following:
    1. Disease activity (e.g., pain, fatigue, inflammation, stiffness); or
    2. Lab values (erythrocyte sedimentation rate, C-reactive protein level); or
    3. Function; or
    4. Axial status (e.g., lumbar spine motion, chest expansion); or
    5. Total active (swollen and tender) joint count; and
2. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

<u>Ulcer of the mouth associated with Behcet's syndrome</u>

INITIAL CRITERIA: Apremilast (Otezla®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of ulcer of the mouth associated with Behcet's syndrome; and
2. Member has active oral ulcers; and
3. Member is 18 years of age or older; and
4. Prescribed by or in consultation with a rheumatologist or dermatologist; and
5. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate systemic corticosteroids, topical corticosteroids or topical sucralfate; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Apremilast (Otezla®) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by ONE of the following:
    a. Reduction in pain from oral ulcers from baseline; or
    b. Reduction in number of oral ulcers from baseline; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

<u>Deficiency of Interleukin-1 Receptor Antagonist</u>

INITIAL CRITERIA: Rilonacept (Arcalyst®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes) confirming the use for the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA); and
2. Member is currently in remission (e.g., no fever, skin rash, and bone pain; no radiological evidence of active bone lesions; C-reactive protein [CRP] less than 5 mg/L); and
3. Member weights at least 10kg; and
4. Prescribed by or in consultation with a rheumatologist or pediatric specialist; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Anakinra (Kineret®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA); and
2. Prescribed by or in consultation with a rheumatologist or pediatric specialist; and
3. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist); and
4. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Rilonacept (Arcalyst®) or anakinra (Kineret®) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Recurrent pericarditis

INITIAL CRITERIA: Rilonacept (Arcalyst®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming use for the treatment of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart and reduction in risk of recurrence; and
2. Member is 12 years of age or older; and
3. Submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate at least one of the following:
    a. NSAID (e.g., ibuprofen, naproxen); or
    b. Colchicine; or
    c. Corticosteroids (e.g., prednisone); and
4. Prescribed by or in consultation with a cardiologist; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Rilonacept (Arcalyst®) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Systemic sclerosis-associated interstitial lung disease

INITIAL CRITERIA: preferred tocilizumab product[3] is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) confirmed by a High-Resolution CT scan or biopsy; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a pulmonologist or rheumatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Preferred tocilizumab product[3] is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Active enthesitis-related arthritis

INITIAL CRITERIA: Secukinumab (Cosentyx®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active enthesitis-related arthritis (ERA); and
2. Member 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 an inadequate response or inability to tolerate TWO different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Secukinumab (Cosentyx®) is medically necessary when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Reduction in the total active (swollen and tender) joint count from baseline; or
    b. Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Atopic dermatitis

INITIAL CRITERIA: Upadacitinib (Rinvoq™) is medically necessary when ALL of the following are met:

1. Diagnosis of refractory, moderate to severe atopic dermatitis; and
2. One of the following:
    a. Involvement of at least 10% body surface area (BSA); or
    b. SCORing Atopic Dermatitis (SCORAD) index value of at least 25; and
3. Member is 12 years of age or older; and
4. Prescribed by or in consultation with a dermatologist, allergist or immunologist; and
5. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following:
    a. Topical steroids, medium potency or higher; or
    b. Topical tacrolimus; or
    c. Topical pimecrolimus; or

d. Eucrisa™; and
e. Opzelura; and

6. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE systemic drug product for the treatment of atopic dermatitis (example include, but are not limited to Adbry [tralokinumab-Idrm], Dupixent [dupilumab], etc.); and
7. No concurrent therapy with any other biologic agents (e.g., JAK inhibitors); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Abrocitinib (Cibinqo™) is medically necessary when ALL of the following are met:

1. Diagnosis of refractory, moderate to severe atopic dermatitis; and
2. One of the following:
    a. Involvement of at least 10% body surface area (BSA); or
    b. SCORing Atopic Dermatitis (SCORAD) index value of at least 25; and
3. Member is 12 years of age or older; and
4. Prescribed by or in consultation with a dermatologist, allergist or immunologist; and
5. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following:
    a. Topical steroids, medium potency or higher; or
    b. Topical tacrolimus; or
    c. Topical pimecrolimus; or
    d. Eucrisa™; and
    e. Opzelura; and
6. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to Adbry [tralokinumab-Idrm], Dupixent [dupilumab], etc.); and
7. No concurrent therapy with any other biologic agents (e.g., JAK inhibitors); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Tralokinumab-idrm (Adbry™) is medically necessary when ALL of the following are met:

1. Member is 12 years of age or older; and
2. Diagnosis of moderate-severe atopic dermatitis; and
3. One of the following:
    a. Involvement of at least 10% body surface area (BSA); or
    b. SCORing Atopic Dermatitis (SCORAD) index value of at least 25; and
4. Prescribed by or in consultation with a dermatologist, allergist or immunologist; and
5. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following:
    a. Topical steroids, medium potency or higher; or
    b. Topical tacrolimus; or
    c. Topical pimecrolimus; or
    d. Eucrisa ™; and
    e. Opzelura; and

6. No concurrent therapy with any other biologic agents; and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

I**NITIAL CRITERIA**: Lebrikizumab-lbkz (Ebglyss™), nemolizumab-ilto (Nemluvio®) is medically necessary when ALL of the following are met:

1. Member is 12 years of age or older; and
2. Diagnosis of moderate-severe atopic dermatitis; and
3. One of the following:
    1. Involvement of at least 10% body surface area (BSA); or
    2. SCORing Atopic Dermatitis (SCORAD) index value of at least 25; and
4. Prescribed by or in consultation with a dermatologist, allergist or immunologist; and
5. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following:
    1. Topical steroids, medium potency or higher; or
    2. Topical tacrolimus; or
    3. Topical pimecrolimus; or
    4. Eucrisa®; and
    5. Opzelura; and
6. ONE of the following:
    1. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or inability to tolerate TWO of the following:
        1. Adbry (tralokinumab-idrm)
        2. Dupixent (dupilumab)
        3. Cibinqo (abrocitinib)
        4. Rinvoq (upadacitinib); or
    2. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested drug, defined as no more than a 45-day gap in therapy; and
7. No concurrent therapy with any other biologic agents; and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Upadacitinib (Rinvoq™), abrocitinib (Cibinqo™), tralokinumab-idrm (Adbry™), lebrikizumab-lbkz (Ebglyss™), nemolizumab-ilto (Nemluvio®) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity); and
2. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Multiple sclerosis

INITIAL CRITERIA: Ozanimod (Zeposia®) is medically necessary when BOTH of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming diagnosis of a relapsing

form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions); and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Ozanimod (Zeposia®) is medically necessary when both of the following are met:
1. Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression); and
2. ONE of the following:
    1. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    2. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Alopecia Areata

INITIAL CRITERIA: Baricitinib (Olumiant®) is medically necessary when all of the following are met:
1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of alopecia areata; and
2. Member is 18 years of age or older; and
3. Member has at least 50% scalp hair loss; and
4. Other causes of hair loss have been rules out (e.g., androgenetic alopecia, trichotillomania, tinea capitis, psoriasis); and
5. Prescribed by or in consultation with a dermatologist; and
6. No concurrent therapy with any other biological agent (e.g., JAK inhibitors); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Ritlecitinib (Litfulo™) is medically necessary when all of the following are met:
1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of alopecia areata; and
2. Member is 12 years of age or older; and
3. Member has at least 50% scalp hair loss; and
4. Other causes of hair loss have been rules out (e.g., androgenetic alopecia, trichotillomania, tinea capitis, psoriasis); and
5. Prescribed by or in consultation with a dermatologist; and
6. No concurrent therapy with any other biological agent (e.g., JAK inhibitors); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Baricitinib (Olumiant ®), Ritlecitinib (Litfulo™) is medically necessary when BOTH of the following are met:
1. Documentation of positive clinical response to therapy; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Polymyalgia Rheumatica

INITIAL CRITERIA: Sarilumab (Kevzara®) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes) confirming a diagnosis of polymyalgia rheumatica (PMR); and
2. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate corticosteroids (e.g., prednisone); and
3. Prescribed by or in consultation with a rheumatologist; and
4. Member is 18 years of age or older; and
5. No concurrent therapy with other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Sarilumab (Kevzara®) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Improvement in symptoms (e.g., pain, stiffness) or lab values (e.g., C-reactive protein) from baseline; or
    b. Reduced need for corticosteroids (e.g., Prednisone), and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Prurigo Nodularis

INITIAL CRITERIA: Nemolizumab-ilto (Nemluvio®) is medically necessary when ALL of the following are met:

1. Submission of documentation (e.g., chart notes) confirming a diagnosis of Prurigo Nodularis (PN); and
2. Member is 18 years of age or older; and
3. Member has at least 20 nodular lesions; and
4. Paid claims or submission of documentation (e.g., chart notes) confirming inadequate response or inability to tolerate one previous PN treatment (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin); and
5. ONE of the following:
    a. Paid claims or submission of documentation (e.g., chart notes) confirming inadequate response or inability to tolerate dupilumab (Dupixent); or
    b. Paid claims or submission of documentation (e.g., chart notes) confirming a continuation of therapy with the requested drug, defined as no more than a 45-day gap in therapy; and
6. Prescribed by or in consultation with allergist, immunologist or dermatologist; and
7. No concurrent therapy with any other biologic agents; and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Nemolizumab-ilto (Nemluvio®) is medically necessary when ALL of the following are met:

1. Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:
    a. Reduction in the number of nodular lesions from baseline; or
    b. Improvement in symptoms (e.g., pruritus, inflammation) from baseline; and
2. ONE of the following:
    a. Dosing and frequency does not exceed maximum FDA recommendation per indication requested; or
    b. Member is continuing on the established dose and frequency previously approved

Reauthorization duration: 12 months

Approval Date: 05/2026

Field Name	Field Description
Prior Authorization Group Description	**Immunosuppressants for Lupus Nephritis**
Drugs	Lupkynis (voclosporin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be rheumatologist, nephrologist or other specialist in the treatment of autoimmune disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date 2/2026	**Initial Authorization** • Member must have a diagnosis of systemic lupus erythematosus (SLE) with a kidney biopsy indicating a histologic diagnosis of lupus nephritis (LN) Class III, IV, or V • Documentation that the member has a baseline eGFR > 45 mL/min/1.73m^2 • Documentation of the member's urine protein/creatinine ratio (UPCR) is provided • Member is concurrently being treated with background immunosuppressive therapy, or has a medical reason for not using background immunosuppressive therapy • Member is NOT concurrently being treated with cyclophosphamide • Medication is prescribed at an FDA approved dose **Reauthorization** • Documentation of improvement in renal function (i.e. reduction in UPCR or no confirmed decrease from baseline eGFR ≥ 20%) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Insulin human, inhalation (Afrezza®)

Applicable Drugs:

Brand Name	Generic Name
Afrezza®	Insulin human, inhalation

Policy:

INITIAL CRITERIA: Afrezza® is medically necessary when ALL of the following are met:

1. Member is 18 years of age or older; and
2. One of the following:
    a. Both of the following:
        1. Diagnosis of type I diabetes mellitus; and
        2. Used in combination with a long-acting insulin (e.g., Lantus)
    b. Diagnosis of type II diabetes mellitus; and
3. Spirometry (FEV1) completed prior to initiation of therapy to identify potential lung disease (must provide the result); and
4. Member is a non-smoker for a minimum of 6 months; and
5. Absence of chronic lung disease such as asthma or chronic obstructive pulmonary disease; and
6. Prescribed by or in consultation with an endocrinologist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERA: Afrezza® is medically necessary when the following are met:

1. There is documentation of spirometry value (FEV_1) has not declined ≥ 20% from baseline; and
2. There is documentation of positive clinical response to therapy

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Insulin Policy

Applicable Drugs:

Brand Name	**Generic Name**
Basaglar TMPO®	Insulin Glargine
Humalog TMPO®	Insulin Lispro
Insulin aspart	
Insulin glargine	
Levemir®	Insulin Detemir
Lyumjev TMPO®	Insulin Lispro-aabc
Novolin® Relion	Insulin Regular
Novolog® Relion	Insulin aspart
Semglee®	Insulin Glargine-yfgn
Tresiba®	Insulin Degludec
Insulin Degludec	

Policy:

Humalog TMPO®, Lyumjev TMPO®, Novolog Relion, Novolin Relion or Insulin aspart is medically necessary when ALL of the following are met:

1. Diagnosis of diabetes mellitus; and
2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following:
    a. Novolin®
    b. Novolog®

c. Humalog®/Insulin lispro

d. Lyumjev®

e. Fiasp®

f. Apidra®

g. Admelog®

h. Humulin®

Authorization duration: 2 years

Basaglar TMPO®, Levemir®, Tresiba®, Insulin Degludec, Insulin glargine-YFGN/Semglee®, or Insulin Glargine is medically necessary when ALL of the following are met:

1. Diagnosis of diabetes mellitus; and
2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate THREE of the following:
    a. Lantus®
    b. Toujeo®
    c. Basaglar®
    d. Rezvoglar®

Authorization duration: 2 years

P&T Approval Date: 2/2026

Title: Interferon Gamma-1b (Actimmune)

Applicable Drugs:

Brand Name	Generic Name
Actimmune®	Interferon gamma-1b

Policy:

INITIAL CRITERIA: Interferon gamma-1b (Actimmune®) is medically necessary when ONE of the following is met:

1. Diagnosis of chronic granulomatous disease (CGD); or
2. Diagnosis of severe, malignant osteopetrosis (SMO)

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Interferon gamma-1b (Actimmune®) is medically necessary when there is documentation of positive clinical response to therapy (i.e., delay of malignant osteopetrosis disease progression; reduction in the frequency and severity of serious infections associated with Chronic Granulomatous Disease)

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Intranasal Corticosteroids

Applicable Drugs:

	beclomethasone
Dymista®	azelactine hydrochloride and fluticasone propionate
Qnasl®	beclomethasone dipropionate
Qnasl®Childrens	beclomethasone dipropionate
Xhance™	Fluticasone propionate
Ryaltris®	olopatadine hydrochloride and mometasone furoate monohydrate

Policy:

Nasal polyps

INITIAL CRITERIA: Fluticasone propionate (Xhance™) is approved when BOTH of the following are met:

1. Diagnosis of nasal polyps; and
2. Submission of documentation (e.g., chart note) or paid claim history showing inadequate response or inability to tolerate generic fluticasone propionate (trial for at least 90 days within the previous 365 days)

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Fluticasone propionate (Xhance®) is reapproved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 12 months

Allergic Rhinitis

INITIAL CRITERIA: Children's Qnasl®*, azelastine hydrochloride and fluticasone propionate (Dymista), Qnasl®, or Ryaltris® is approved when BOTH of the following are met:

1. Diagnosis of allergic rhinitis; and
2. Inadequate response or inability to tolerate BOTH of the following generic nasal sprays:

1. Flunisolide; and
2. Fluticasone propionate

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Children's Qnasl®*, azelastine hydrochloride and fluticasone propionate (Dymista®), Qnasl®, or Ryaltris® is re-approved when there is documentation of positive clinical response to therapy.
Reauthorization duration: 12 months

*Fluticasone propionate is approved for children under 6 years of age

Chronic rhinosinusitis without nasal polyps

INITIAL CRITERIA: Fluticasone propionate (Xhance™) is approved when BOTH of the following are met:

1. Diagnosis of chronic rhinosinusitis without nasal polyps; and
2. Submission of documentation (e.g., chart notes) or paid claim history showing inadequate response or inability to tolerate generic fluticasone propionate (trial of at least 90 days within the previous 365 days)

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Fluticasone propionate (Xhance™) is medically necessary with documentation of positive clinical response to therapy

Reauthorization duration: 12 months

P&T Approval Date: 2/2026

Title: Leniolisib (Joenja)

Applicable Drugs:

Brand Name	Generic Name
Joenja®	Leniolisib

Policy:

INITIAL CRITERIA: Leniolisib (Joenja®) is medically necessary when all of the following are met:

1. Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS); and
2. Molecular genetic testing confirms mutations in the PIK3CD or PIK3R1 gene; and
3. Member is 12 years of age or older; and
4. Member weighs greater than or equal to 45kg; and
5. Both of the following:
    1. Presence of nodal and/or extranodal proliferation (e.g., lymphadenopathy, splenomegaly, hepatomegaly); and
    2. Presence of other clinical findings and manifestations consistent with APDS (e.g., recurrent sino-pulmonary infections, bronchiectasis, enteropathy); and
6. Inadequate response or inability to tolerate at least one standard of care treatment for APDS (e.g., Immunoglobulin replacement therapy, antimicrobial prophylaxis [e.g., azithromycin, Bactrim], rituximab, tacrolimus, etc.); and
7. Prescribed by or in consultation with one of the following:
    1. Hematologist; or
    2. Immunologist; or
    3. Geneticist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Leniolisib (Joenja®) is medically necessary with documentation of positive clinical response to therapy (e.g., reduced lymph node size, increased naïve B-cell percentage, decreased severity or frequency of infections/hospitalizations)

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Prior Authorization Group Description	**Loargys (pegzilarginase-nbln)**
Drugs	Loargys (pegzilarginase-nbln)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist or specialist experienced in Urea Cycle Disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For reauthorization, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 05/2026
	<u>Initial Authorization:</u>
	• Medication is prescribed at an FDA approved dose
	• Documentation of patient weight
	• Diagnosis of Arginase 1 Deficiency (ARG1-D) confirmed by one of the following:
	  o Pathogenic variants in ARG1 (copy of genetic results must be submitted with request)
	  o Elevated plasma arginine (pArg)
	  o Diminished erythrocyte ARG1 activity
	• Provider attestation member will use the drug in conjunction with a protein restricted diet
	• Documentation of baseline pArg
	
	<u>Re-Authorization:</u>
	• Documentation of positive clinical response as evidenced by normalization in pArg
	• Documentation of member's weight
	• Medication is prescribed at an FDA approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Title: Lonafarnib (Zokinvy)

Applicable Drugs:

Brand Name	Generic Name
Zokinvy™	Lonafarnib

Policy:

INITIAL CRITERIA Lonafarnib (Zokinvy™) is medically necessary when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming one of the following:
    1. Diagnosis of Hutchinson-Gilford Progeria Syndrome; or
    2. Genetic testing results confirming a LMNA mutation that results in the production of progerin; or
    3. Processing-deficient Progeroid Laminopathies with one of the following:
        1. Genetic testing results confirming member has a heterozygous LMNA mutation with progerin-like protein accumulation; or
        2. Genetic testing results confirming member has a homozygous or compound heterozygous ZMPSTE24 mutations; and
2. Member is 12 months of age or older; and
3. Member has a body surface are of 0.39 m^2 and above; and
4. Prescribed by or in consultation with a specialist with expertise in the diagnosis and management of Progeria

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Lonafarnib (Zokinvy™) is medically necessary when all of the following have been met:

1. Documentation that member has had clinical benefit with the requested drug; and
2. Prescribed by or in consultation with a specialist with expertise in the diagnosis and management of Progeria

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Mannitol (Bronchitol®)

Applicable Drugs:

Brand Name	Generic Name
Bronchitol®	Mannitol

Policy:

INITIAL CRITERIA: Mannitol (Bronchitol®) is approved when all of the following are met:

1. Diagnosis of cystic fibrosis; and
2. Member is 18 years of age or older; and
3. Member has passed the Bronchitol Tolerance Test (BTT); and
4. Member has inadequate response or inability to tolerate ONE of the following:
    1. Inhaled hypertonic saline; or
    2. Pulmozyme (dornase alfa); and
5. Prescribed by or in consultation with one of the following:
    1. Pulmonologist; or
    2. Specialist associated with a cystic fibrosis care center

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Mannitol (Bronchitol®) is re-approved when there is documentation of positive clinical response to therapy (e.g. improvement in lung function [forced expiratory volume in one second {FEV1}])
Reauthorization duration: 2 years

P&T Approval Date: 2/2026

Title: Maralixibat (Livmarli)

Applicable Drugs:

Brand Name	Generic Name
Livmarli™	maralixibat

Policy:

Alagille Syndrome (ALGS)

INITIAL CRITERIA Maralixibat (Livmarli®) is medically necessary when ALL of the following are met:

1. Diagnosis of Alagille Syndrome (ALGS) as confirmed by BOTH of the following:
    1. Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene; and
    2. One of the following:
        1. Total serum bile acid > 3x the upper limit of normal (ULN); or
        2. Conjugated bilirubin > 1 mg/dL; or
        3. Fat soluble vitamin deficiency otherwise unexplainable; or
        4. Gamma-glutamyl transpeptidase (GGT) > 3x ULN; and
2. Member is experiencing moderate to severe cholestatic pruritus; and
3. Member is 3 months of age or older; and
4. Prescribed by or in consultation with a hepatologist or gastroenterologist; and
5. Member has had an inadequate response or inability to tolerate at least two of the following treatments used for the relief of pruritus:
    1. Ursodeoxycholic acid (e.g., Ursodiol); or
    2. Antihistamines (e.g., diphenhydramine, hydroxyzine); or
    3. Rifampin; or
    4. Bile acid sequestrants (e.g., cholestyramine, colestipol, colesevelam)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Maralixibat (Livmarli™) is medically necessary with

documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score)

Reauthorization duration: 2 years

Progressive Familial Intrahepatic Cholestasis (PFIC)

INITIAL CRITERIA: Maralixibat (Livmarli™) is medically necessary when ALL of the following are met:

1. Both of the following:
    1. Diagnosis of Progressive familial intrahepatic cholestasis (PFIC); and
    2. Molecular genetic testing confirms mutations in the ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, or MYO5B; and
2. Member is experiencing both of the following:
    1. Moderate to severe pruritus; and
    2. Member has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory; and
3. Member is 12 months of age or older; and
4. Member has had an inadequate response to at least two of the following treatments used for the relief of pruritus:
    1. Ursodeoxycholic acid (e.g., Ursodiol)
    2. Antihistamines (e.g., diphenhydramine, hydroxyzine)
    3. Rifampin
    4. Bile acid sequestrants (e.g., Questran, colestid, Welchol); and
5. Prescribed by or in consultation with one of the following:
    1. Hepatologist; or
    2. Gastroenterologist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Maralixibat (Livmarli™) is medically necessary with documentation of positive clinical response to therapy (e.g., reduced serum bile acids, improved pruritus)

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Mavorixafor (Xolremdi)

Applicable Drugs:

Brand Name	Generic Name
Xolremdi	Mavorixafor

Policy:

INITIAL CTITERIA: Mavorixafor (Xolremdi™) is medically necessary when ALL of the following are met:

1. Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome; and
2. Member 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. Member has an absolute neutrophil count (ANC) less than or equal to 500 cells /µL; and
4. Member is 12 years of age or older; and
5. Prescribed by or in consultation with one of the following:
    1. Immunologist
    2. Hematologist
    3. Geneticist
    4. Allergist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Mavorixafor (Xolremdi™) is medically necessary with documentation of positive clinical response to therapy (e.g., improvement in ANC, reduction in infections)

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Title: Mecasermin (Increlex®)

Applicable Drugs:

Brand Name	Generic Name
Increlex®	mecasermin

Policy:

INITIAL CRITERIA: Mecasermin (Increlex®) is medically necessary when all of the following are met:

1. Diagnosis of growth failure in children with ONE of the following:
    a. All of the following:
        1. Severe primary insulin-like growth factor-1 deficiency (IGF-D); and
        2. Height standard deviation (SD) score of less than or equal to 3.0 SD scores below normal (growing at below the third percentile for age and sex); and
        3. Baseline IGF-1 (SD) score of less than or equal to 3.0 SD scores below normal (based on age- and sex-related reference ranges); and
        4. Normal or elevated GH level (based on GH stimulation testing); or
    b. Both of the following:
        1. Growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH; and
        2. Measured titers of GH-neutralizing antibodies; and
2. Member is 2 years of age or older; and
3. Open epiphyses (bone growth plates) (bone age less than 14 years for girls and less than 16 years for boys); and
4. Prescribed by or in consultation with an endocrinologist

Initial Authorization duration: 12 months

CONTINUATION CRITERIA: Continuation of mecasermin (Increlex®) is medically necessary when all of the following are met:

1. Growth velocity greater than or equal to 2 cm/year; and

2. Yearly evaluation by an endocrinologist; and
3. BOTH of the following
    a. Expected adult height is not obtained; and
    b. Documentation of expected adult height goal

Continuation duration: 12 months

P&T Approval Date: 11/2025

Title: Medical injectable medications covered under the pharmacy benefit

Policy:

Coverage is subject to the terms, conditions, and limitations of the member's contract.

The following medications are covered under the medical benefit:

1. Cyanocobalamin (vitamin B12) injection
2. Heparin injection
3. Hydrocortisone injection
4. Methotrexate injection (vial)
5. Non-insulin syringes/needles

A benefit exception will be made to cover cyanocobalamin injection, heparin injection, hydrocortisone injection, methotrexate vials under the prescription drug benefit when ALL of the following are met:

1. The requested drug is being used for a Food and Drug Administration approved indication or compendium supported indication as outlined in Off-label Use policy; and
2. The prescriber assumes responsibility for teaching the member proper preparation, administration and disposal; and
3. The prescriber provides a statement indicating the reason prescription drug benefit products are not an option, and
4. ONE of the following:
    1. Provider does not stock the requested medication; or
    2. Access at the provider's office is not feasible due to frequency of administration

A benefit exception will be made to cover non-insulin syringes/needles under the prescription drug benefit when required to administer an injectable medication and not supplied with the product.

Coverage is subject to the terms of the member's prescription drug benefit, including but not limited to cost-share.

Authorization duration: 2 years

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Medications without Drug or Class Specific Criteria**
Drugs	• Medications without drug or class specific prior authorization criteria • Brand drugs and reference biologics when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available ***The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Puberty blocking medications (Supprelin, Lupron, etc.) and hormone replacement therapy (Estradiol, Testosterone, etc.) used for treatment of gender dysphoria for children under the age of 19
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for up to 12 months (depending on the diagnosis and usual treatment duration).
Other Criteria	**Initial Authorization:** **All Requests:** • The drug is requested for an appropriate use (per the references outlined in "Covered Uses") • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") • Patient meets one of the three following criteria: o Documented trial and failure or intolerance of two alternative formulary/preferred medications appropriate for the requested use (per the references outlined in "Covered Uses" or has a medical reason why these drug(s) cannot be used [e.g. intolerance, contraindication]). For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. o No other preferred medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia. o All other preferred medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy. **Brand drugs with a therapeutically equivalent (A-rated) generic drug currently available:** • The provider either verbally or in writing has submitted a medical or member specific reason why the brand name drug is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to the generic drug, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid this drug. The MedWatch form must be included with the prior authorization request Form FDA 3500 – Voluntary Reporting

Revision/Review Date 10/2026	**Reference biologic drugs with either a biosimilar or interchangeable biologic drug currently available:** • The prescriber has verbally or in writing submitted a medical or member specific reason why the reference biologic is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to two (if available) biosimilar or interchangeable biologics, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization • The currently available biosimilar product(s) does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested Form FDA 3500 – Voluntary Reporting **Reauthorization:** • Documentation of provider attestation that demonstrates a clinical benefit • The requested drug is for a medically accepted dose as outlined in Covered Uses **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Title: Metabolic Disorder agents (Strensiq, Xuriden)

Applicable Drugs:

Brand Name	Generic Name
Strensiq® Xuriden®	asfotase alfa uridine triacetate

Policy:

Perinatal/infantile or juvenile-onset hypophosphatasia

INITIAL CRITERIA: Asfotase alfa (Strensiq®) is medically necessary when ALL of the following are met:

1. Submission of documentation (e.g., chart note) confirming diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia (HPP); and
2. Prescribed by or in consultation with a medical geneticist or other specialist that treats inborn errors of metabolism (e.g., endocrinologist, rheumatologist, geneticist, orthopedist); and
3. For member requesting the 80mg/0.8ml vial: submission of documentation confirming the member's weight is greater than or equal to 40kg; and
4. Submission of medical records (e.g., chart notes) documenting onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures); and
5. Submission of medical records (e.g., chart notes) documenting radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., infantile rickets, craniosynostosis, non-traumatic fractures, osteoporosis or low bone mineral content for age [as detected by DEXA]); and
6. Submission of medical records (e.g., chart notes) documenting one of the following:
    a. Both of the following:
        1. Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range; and

2. Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level]); or

b. Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing; and

7. Requested dose will not exceed the following: (Note to prescriber: Three times a week dosing leads to less waste and may lead to less injection site reactions compared to six times a week dosing)

b. 9 mg/kg per week for perinatal/infantile-onset HPP

c. 6 mg/kg per week for juvenile-onset HPP

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Asfotase alfa (Strensiq®) is medically necessary when ALL of the following are met:

1. There is positive clinical response to therapy as evidenced by one of the following:
    1. Improvement and/or stabilization of clinical signs and/or symptoms of hypophosphatasia (e.g., respiratory status [ventilator free survival], growth) or radiographic findings (e.g., skeletal manifestations); or
    2. Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level]); and
2. Prescribed by or in consultation with a medical geneticist or other specialist that treats inborn errors of metabolism (e.g., endocrinologist, rheumatologist, geneticist, orthopedist); and
3. Requested dose will not exceed the following: (Note to prescriber: Three times a week dosing leads to less waste and may lead to less injection site reactions compared to six times a week dosing)
    1. 9 mg/kg per week for perinatal/infantile-onset HPP
    2. 6 mg/kg per week for juvenile-onset HPP; and
4. For member requesting the 80mg/0.8ml vial: submission of documentation confirming the member's weight is greater than or equal to 40kg

Reauthorization duration: 2 years

Hereditary orotic aciduria

INITIAL CRITERIA: Uridine triacetate (Xuriden®) is medically necessary when ALL of the following are met:

1. Submission of documentation (e.g., chart note) confirming diagnosis of hereditary orotic aciduria; and
2. Prescribed by or in consultation with a medical geneticist or other specialist that treats inborn errors of metabolism

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Uridine triacetate (Xuriden®) is medically necessary when there is positive clinical response to therapy

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Metreleptin (Myalept®)

Brand Name	Generic Name
Myalept®	metreleptin

Policy:

INITIAL CRITERIA: Metreleptin (Myalept®) is medically necessary when ALL of the following are met:

1. Diagnosis of congenital or acquired generalized lipodystrophy (excluding other forms of lipodystrophy); and
2. Prescribed as adjunct to diet as replacement therapy; and
3. Member is refractory to current standards of care for lipid and diabetic management; and
4. Prescribed by or in consultation with an endocrinologist; and
5. Documentation demonstrates that member has at least one of the following metabolic abnormalities:
    a. Insulin resistance (defined as requiring more than 200 units per day)
    b. Hypertriglyceridemia
    c. Diabetes

Initial Authorization duration: 12 months

CONTINUATION CRITERIA: Continuation of metreleptin (Myalept®) is medically necessary when there is documentation of positive clinical response to metreleptin (Myalept®) therapy (e.g., sustained reduction in Hemoglobin A1c or triglycerides from baseline)

Continuation authorization duration: 2 years

P&T Approval Date: 11/2025

Title: Migraine and Headache Agents

Applicable Drugs:

Brand Name	**Generic Name**
Maxalt®/Maxalt® MLT	Rizatriptan
Amerge®	Naratriptan
Frova®	Frovatriptan
Imitrex®, Tosymra®, Onzetra® Xsail, Zembrace® Symtouch	Sumatriptan
Relpax®	Eletriptan
Zomig®/ Zomig® ZMT	Zolmitriptan
Treximet®	Sumatriptan/naproxen
D.H.E. 45®, Migranal®, Trudhesa™	Dihydroergotamine mesylate
Nurtec™ ODT	Rimegepant
Ubrelvy™	Ubrogepant
Reyvow®	Lasmiditan
Aimovig™	Erenumab
Ajovy™	Fremanezumab
Emgality™	Galcanezumab
Qulipta™	Atogepant
Zavzpret™	zavegepant

Policy:

Acute Treatment of Migraine

INITIAL CRITERIA: Frova®, Imitrex®, Tosymra®, Relpax®, Onzetra® Xsail, Zembrace® Symtouch, zolmitriptan nasal spray, or Zomig®/zolmitriptan Zomig® ZMT is medically necessary when ALL of the following are met:

1. Diagnosis of migraine headache; and
2. Use in the age group shown in the table below; and
3. Inadequate response or inability to tolerate two generic triptans (e.g., eletriptan, naratriptan, rizatriptan, zolmitriptan, sumatriptan) as appropriate for the member's age

Drug	Age Recommendation
Rizatriptan	Age 6 and up
Zolmitriptan (Zomig®/Zomig® ZMT)	Age 12 and up
Eletriptan (Relpax®)	Age 18 and up
Naratriptan	Age 18 and up
Sumatriptan (Imitrex®, Onzetra® Xsail, Zembrace® Symtouch, Tosymra®)	Age 18 and up
Frovatriptan (Frova®)	Age 18 and up

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Frova®, Imitrex®, Tosymra®, Relpax®, Onzetra® Xsail, Zembrace® Symtouch, zolmitriptan nasal spray or Zomig®/Zomig® ZMT is medically necessary when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

INITIAL CRITERIA: Sumatriptan/naproxen (Treximet®) is medically necessary when ALL of the following are met:

1. Diagnosis of migraine headache; and
2. Member is 12 years of age or older; and
3. Inadequate response or inability to tolerate three generic triptans (e.g., eletriptan, naratriptan, rizatriptan, zolmitriptan, sumatriptan); and
4. Inadequate response to concurrent administration of sumatriptan and naproxen as separate products

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Sumatriptan/naproxen (Treximet®) is medically necessary when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

INITIAL CRITERIA: Dihydroergotamine mesylate (D.H.E. 45®) injection is medically necessary when ALL of the following are met:

1. Prescribed by or in consultation with one of the following specialists:

a. Neurologist; or
b. Pain specialist; or
c. Headache specialist certified by the United Council of Neurologic Subspecialties; and

2. Diagnosis of acute treatment of migraine or cluster headaches; and
3. Member is 18 years of age or older; and
4. Member has been instructed on proper preparation, injection, and disposal of medication; and
5. ONE of the following:
    a. Inadequate response or inability to tolerate two, oral or nasal, triptans; or
    b. Triptan overuse, defined as using triptans greater than 8 days per month; and
6. For brand D.H.E. 45 only, inadequate response or inability to tolerate generic dihydroergotamine injection or it is not available; and
7. If member has 4 or more headache days per month, member must be currently treated with one of the following, unless there is a contraindication or intolerance to these medications:
    a. An antidepressant (i.e., Elavil [amitriptyline] or Effexor [venlafaxine])
    b. An anticonvulsant (i.e., Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate])
    c. A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
    d. Atacand (candesartan)

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Dihydroergotamine mesylate (D.H.E 45®) injection is medically necessary when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

INITIAL CRITERIA: Dihydroergotamine mesylate (Migranal®) or dihydroergotamine mesylate HFA (Trudhesa™) is medically necessary when ALL of the following are met:

1. Diagnosis of moderate to severe migraine headache with or without aura; and
2. Inadequate response or inability to tolerate TWO, oral or nasal, triptans; and
3. If member has 4 or more headache days per month, member must be currently treated with one of the following, unless there is a contraindication or intolerance to these medications:
    a. An antidepressant (i.e., Elavil [amitriptyline] or Effexor [venlafaxine])
    b. An anticonvulsant (i.e., Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate])
    c. A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
    d. Atacand (candesartan); and
4. Prescribed by or in consultation with one of the following specialists:
    a. Neurologist; or
    b. Pain specialist; or
    c. Headache specialist certified by the United Council of Neurologic Subspecialities; and
5. For dihydroergotamine mesylate HFA (Trudhesa) only, inadequate response or inability to tolerate generic dihydroergotamine mesylate nasal spray

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Dihydroergotamine mesylate (Migranal®) or dihydroergotamine mesylate HFA (Trudhesa™) is medically necessary when ALL of the following are met:

1. Documentation of positive clinical response to therapy; and

2. Prescribed by or in consultation with one of the following specialists:
    1. Neurologist; or
    2. Pain specialist; or
    3. Headache specialist certified by the United Council of Neurologic Subspecialities; and
3. For dihydroergotamine mesylate HFA (Trudhesa) only, inadequate response or inability to tolerate generic dihydroergotamine mesylate nasal spray

Reauthorization duration: 2 years

INITIAL CRITERIA: Rimegepant (Nurtec™ ODT), ubrogepant (Ubrelvy™), zavegepant (Zavzpret) or lasmiditan (Reyvow®) is medically necessary when all of the following are met:

1. Diagnosis of migraine with or without aura; and
2. Will be used for the acute treatment of migraine; and
3. For ubrogepant (Ubrelvy™), zavegepant (Zavzpret™), lasmiditan (Reyvow®) only, will not be used for preventative treatment of migraine; and
4. Member is 18 years of age or older; and
5. Inadequate response or inability to tolerate two triptans (e.g., eletriptan, rizatriptan, sumatriptan); and
6. If the member has 4 or more headache days per month, the member must be on current treatment or have inability to tolerate one of the following:
    a. Elavil (amitriptyline) or Effexor (venlafaxine); or
    b. Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate); or
    c. Beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol); or
    d. Atacand (candesartan); and

7. Medication will not be used in combination with another CGRP antagonist for the acute treatment of migraines; and
8. For Lasmiditan (Reyvow®) and zavegepant (Zavzpret) only, inadequate response or inability to tolerate BOTH rimegepant (Nurtec™ ODT) and ubrogepant (Ubrelvy™)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Rimegepant (Nurtec™ ODT), ubrogepant (Ubrelvy™), zavegepant (Zavzpret) or lasmiditan (Reyvow®) is medically necessary when all of the following are met:

1. Member has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea); and
2. For ubrogepant (Ubrelvy™), zavegepant (Zavzpret™), lasmiditan (Reyvow®) only, will not be used for preventative treatment of migraine; and

3. Medication will not be used in combination with another CGRP antagonist for the acute treatment of migraines

Reauthorization duration: 2 years

Preventative Treatment of Episodic or Chronic Migraine with Injectable CGRP Antagonists

INITIAL CRITERIA: Erenumab (Aimovig™), fremanezumab (Ajovy™), or galcanezumab (Emgality™) 120mg/ml is medically necessary when ALL of the following are met:

1. Member is 18 years of age or older; and
2. ONE of the following:

1. Diagnosis of episodic migraines defined as 4-14 headache days per month and inadequate response or inability to tolerate at least a two-month trial of TWO of the following prophylactic medications:
    1. Topiramate
    2. Divalproex sodium/ valproic acid
    3. Beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol
    4. Tricyclic antidepressants: amitriptyline, nortriptyline
    5. SNRI antidepressants: venlafaxine, duloxetine; or
    6. Candesartan (Atacand); or
2. Diagnosis of chronic migraines defined as 15 or more headache days per month and inadequate response or inability to tolerate at least a two-month trial of TWO of the following prophylactic medications:
    1. Topiramate
    2. Divalproex sodium/valproic acid
    3. Beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol
    4. Tricyclic antidepressants: amitriptyline, nortriptyline
    5. SNRI antidepressants: venlafaxine, duloxetine; or
    6. Trial of additional prophylactic medications does not apply if member has previously been treated with Onabotuliniumtoxin A (Botox) for migraines; and
3. Medication overuse headache has been considered, and potentially offending medication(s) have been discontinued; and
4. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines; and
5. For galcanezumab (Emgality™ 120mg/ml) only, inadequate response or inability to tolerate BOTH erenumab (Aimovig™) and fremanezumab (Ajovy™)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Erenumab (Aimovig™), fremanezumab (Ajovy™), or galcanezuma (Emgality™) 120mg/ml is medically necessary when ALL of the following are met:

1. Documentation of response to therapy as defined by 50% reduction in headache days per month from baseline (defined as at least 4 hours duration and moderate intensity); and
2. For galcanezumab (Emgality™ 120mg/ml) only, inadequate response or inability to tolerate BOTH erenumab (Aimovig™) and fremanezumab (Ajovy™); and
3. Use of acute migraine medication (e.g., nonsteroidal anti-inflammatory drugs (NSAID) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan) has decreased since the start of CGRP therapy; and
4. For Chronic migraine only: member continues to be monitored for medication overuse headache (MOH); and
5. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Reauthorization duration: 2 years

Preventative Treatment of Episodic Migraines with Oral CGRP Antagonist

INITIAL CRITERIA: Rimegepant (Nurtec™ ODT) or atogepant (Qulipta™) is medically necessary when all of the following are met:

1. Both of the following:
    1. Diagnosis of episodic migraines; and
    2. One of the following:
        1. For Nurtec ODT only, member has 4 to 18 migraine days per month, but no more than 18 headache days per month; or
        2. For Qulipta only, Member has 4 to 14 migraine days per month, but no more than 14 headache days per month; and
2. Member is 18 years of age or older; and
3. Two of the following:
    1. Inadequate response or inability to tolerate at least a two-month trial of Elavil (amitriptyline) or Effexor (venlafaxine); or
    2. Inadequate response or inability to tolerate at least a two-month trial of Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate); or
    3. Inadequate response or inability to tolerate at least a two-month trial of one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol; and
    4. Inadequate response or inability to tolerate at least a two-month trial of Atacand (candesartan); and

4. Medication will not be used in combination with another CGRP antagonist for the preventative treatment of migraines

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Rimegepant (Nurtec™ ODT) or atogepant (Qulipta™) is medically necessary when all of the following are met:

1. Member has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity; 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 antagonist for the preventative treatment of migraines

Reauthorization duration: 2 years

Preventive treatment of Chronic Migraine with Oral CGRP Antagonist

INITIAL CRITERIA: Atogepant (Qulipta™) is medically necessary when all of the following are met:

1. Diagnosis of chronic migraines defined as 15 or more headache days per month, of which at least 8 must be migraine days for at least 3 months; and
2. Inadequate response or inability to tolerate at least two-month trial of TWO of the following prophylactic medications:
    a. Tricyclic antidepressants: amitriptyline, nortriptyline
    b. Topiramate
    c. Divalproex sodium/valproic acid

d. Beta blocker: metoprolol, propranolol, timolol, atenolol, nadolol
e. SNRI antidepressants; venlafaxine, duloxetine
f. Candesartan (Atacand)

3. Trial of additional prophylactic medications does not apply if member has previously been treated with Onabotuliniumtoxin A (Botox) for migraines; and
4. Member is 18 years of age or older; and
5. Medication will not be used in combination with another CGRP inhibitor for the preventative treatment of migraines; and
6. Medication overuse headache has been considered, and potentially offending medication(s) have been discontinued

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Atogepant (Qulipta™) is medically necessary when all of the following are met:

1. Member has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity; 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. Member continues to be monitored for medication overuse headache (MOH); and
4. Medication will not be used in combination with another CGRP inhibitor for the preventative treatment of migraines

Reauthorization duration: 2 years

Episodic Cluster Headaches

INITIAL CRITERIA: Galcanezumab (Emgality™) 100mg/ml is medically necessary when ALL of the following are met:

1. Diagnosis of episodic cluster headache; and
2. Member has experienced at least 2 cluster periods lasting 7 days to 365 days, separated by pain-free periods lasting at least three months; and
3. Member is 18 years of age or older; and
4. Medication will not be used in combination with another CGRP antagonist

Initial authorization duration: 3 months

REAUTHORIZATION CRITERIA: Galcanezumab (Emgality™) 100mg/ml is medically necessary when ALL of the following are met:

1. Member has experienced a positive clinical response to therapy, demonstrated by a reduction in headache frequency and/or intensity; and
2. Medication will not be used in combination with another CGRP antagonist

Reauthorization duration: 12 months

Title: Nedosiran (Rivfloza™)

Applicable Drugs:

Brand Name	Generic Name
Rivfloza™	Nedosiran

Policy:

INITIAL CRITERIA: Nedosiran (Rivfloza™) is approved when ALL of the following are met:

1. Diagnosis of primary hyperoxaluria type 1 (PH1); and
2. Disease has been confirmed by both of the following:
    1. One of the following:
        1. Elevated urinary oxalate excretion; or
        2. Elevated plasma oxalate concentration; or
        3. Spot urinary oxalate to creatinine molar ratio greater than normal for age; and
    2. One of the following:
        1. Genetic testing demonstrating a mutation in the alanine: glyoxylate aminotransferase (AGXT) gene; or
        2. Liver biopsy demonstrating absence or reduced alanine: glyoxylate aminotransferase (AGT) activity; and
3. Member is 2 years of age or older; and
4. Member has preserved kidney function (e.g., eGFR greater than or equal to 30 ml/min/1.72m^2); and
5. Member has not received a liver transplant; and
6. Prescribed by or in consultation with one of the following:
    1. Hepatologist
    2. Nephrologist
    3. Urologist
    4. Geneticist

5. Specialist with expertise in the treatment of PH1

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Nedosiran (Rivfloza™) is re-approved when ALL of the following are met:

1. Member demonstrates positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration); and
2. Member has not received a liver transplant; and
3. Prescribed by or in consultation with one of the following:
    1. Hepatologist
    2. Nephrologist
    3. Urologist
    4. Geneticist
    5. Specialist with expertise in the treatment of PH1

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Niemann-Pick Disease Type C**
Drugs	Miplyffa (arimoclomol), Aqneursa (levacetylleucine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Concomitant use of Miplyffa and Aqneursa
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a neurologist, geneticist, or specialist in the treatment of Niemann-Pick disease type C (NPC)
Coverage Duration	If all criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 2/2026
	<u>Initial Authorization</u>
	• Diagnosis of NPC as confirmed by genetic testing demonstrating one of the following:
	  o Mutations in both alleles of NPC1 gene or NPC2 gene
	  o Mutation in one allele of NPC1 or NPC2 AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2x the upper limit of normal)
	• Documentation that member has at least one neurological sign of NPC (i.e., cognitive decline, vertical supranuclear gaze palsy, ataxia, seizures, etc.)
	• Documentation that member is ambulatory
	• For Miplyffa, prescriber must also attest that member will use in combination with miglustat
	• Member's weight
	• Request is for an FDA-approved dose
	
	<u>Reauthorization</u>
	• Documentation of positive clinical response to therapy (i.e., improvement or stabilization in ambulation, fine motor skills, swallowing, or speech)
	• Member's weight
	• Request is for an FDA-approved dose
	
	Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Nitisinone Products**
Drugs	Formulary: Nitisinone (Orfadin) capsules Orfadin suspension Nityr (nitisinone) tablets Non-Formulary: Harliku (nitisinone) tablets Any other marketed agent within this class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a specialist in inherited metabolic diseases
Coverage Duration	If all of the criteria are met, the request will be approved for up to 12 months.
Other Criteria	**Initial Authorization** • For alkaptonuria (AKU) (Harliku and generic nitisinone only): o Diagnosis of AKU confirmed by one of the following: ▪ Urinary homogentisic acid (HGA) excretion of >0.4 g/24 hours ▪ Genetic testing reveals variations in the homogentisate 1,2 dioxygenase (HGD) gene o Documented clinical manifestation of AKU (e.g. urine that darkens when exposed to air, ochronosis, chronic joint pain) o For Harliku, documented trial and failure, or intolerance to treatment with generic nitisinone prescribed at a dose for the treatment of AKU o Drug is prescribed at an FDA-approved dose or dose is supported by compendia or standard of care guideline • For hereditary tyrosinemia type 1 (all nitisinone products EXCEPT Harliku): o Diagnosis of hereditary tyrosinemia type 1 confirmed by one of the following: ▪ DNA testing ▪ Detection of succinylacetone (SA) in urine or blood test

Revision/Review Date: 11/2025	o Documentation provided attesting to diet restricting tyrosine and phenylalanine o If request is for Nityr tablet or Orfadin suspension, documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic nitisinone (Orfadin) capsule o Drug is prescribed at an FDA approved dose **<u>Reauthorization</u>** • Attestation that member is achieving a clinical benefit from treatment o For Harliku, clinical benefit evidenced by decrease in urinary homogentisic acid [HGA] levels, decrease in visible ochronosis, and/or improvement/stabilization in joint-related symptoms • Drug is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Non-FDA Approved Products

Policy:

Coverage is subject to the terms, conditions, and limitations of the member's contract.

Prescription drugs that are commercially available but not approved by the FDA are not considered a covered benefit.

Some prescription drugs that are not FDA approved, and not otherwise excluded, will be covered under the pharmacy benefit for certain plans as required by the Patient Protection and Affordable Care Act (PPACA) or as defined in the member's benefit booklet. These items include but may not be limited to the following products as listed:

- Prenatal vitamins, oral
- Preventative vitamins and minerals as required by the PPACA
- Cholecalciferol (vitamin D3) 50,000 units*
- Sulfuric acid/phenolsulfonic acid solution*

Some prescription drugs that came to market prior to 1938, prior to the current FDA approval process, and not otherwise excluded, will be covered under the prescription drug benefit if they are deemed medically accepted as defined in the Off-Label Use policy. These items include but may not be limited to the following products as listed:

- Aluminum chloride topical
- Hydrocortisone suppositories
- Hyoscyamine
- Phenobarbital
- Opium tincture
- Morphine suppositories
- Sodium chloride for inhalation
- Homatropine ophthalmic
- Thyroid products (e.g., Armour Thyroid, Nature-Thyroid, NP Thyroid, WP Thyroid)
- Phenazopyridine HCL (Pyridium) 100mg and 200mg tablets
- Nitro-time CPCR

- Salsalate tablet

*Exceptions will be made for these products to meet essential health benefit requirements

P&T Approval Date: 11/2025

Title: Octreotide Products

Applicable Drugs:

Brand Name	Generic Name
Mycapssa	Octreotide

Policy:

ACROMEGALY

INITIAL CRITERIA: Octreotide acetate or octreotide (Mycapssa™) is medically necessary when ALL the following are met:

1. Member is 18 years of age or older; and
2. Diagnosis of acromegaly; and
3. Prescribed by or in conjunction with an endocrinologist; and
    1. Inadequate response to surgery or pituitary irradiation;
4. Inadequate response or inability to tolerate a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses; and
5. For Mycapssa™ only, member has responded to and tolerated treatment with Octreotide or Lanreotide products (e.g., Somatulline Depot, Sandostatin, Sandostatin LAR depot).

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Octreotide aetate or octreotide (Mycapssa™) is medically necessary with documentation of positive clinical response to therapy (e.g., reduction or normalization of IFG-I or Growth Hormone level for same age and sex)

Reauthorization duration: 2 years

CARCINOID TUMORS, FOR SYMPTOMATIC TREATMENT OF DIARRHEA OR FLUSHING

INITIAL CRITERIA: Octreotide acetate is medically necessary when ALL the following are met:

1. Diagnosis of metastatic carcinoid tumor; and

2. Member requires symptomatic treatment of severe diarrhea or flushing episodes; and
3. Member is 18 years of age or older

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Octreotide acetate is medically necessary with documentation of an improvement in the number of diarrhea or flushing episodes.

Reauthorization duration: 2 years

VASOACTIVE INTESTINAL PEPTIDE TUMORS, FOR SYMPTOMATIC TREATMENT OF DIARRHEA

INITIAL CRITERIA: Octreotide acetate is medically necessary when ALL the following are met:

1. Diagnosis of vasoactive intestinal peptide tumor; and
2. Member requires the treatment of profuse watery diarrhea, and
3. Member is 18 years of age or older

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Octreotide acetate is medically necessary with documentation of an improvement in the number of diarrhea episodes.

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Odevixibat (Bylvay)

Applicable Drugs:

Brand Name	Generic Name
Bylvay™	odevixibat

Policy:

Progressive Familial Intrahepatic Cholestasis (PFIC)

INITIAL CRITERIA: Odevixibat (Bylvay™) is medically necessary when ALL of the following are met:

1. Diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC); and
2. Confirmed molecular diagnosis of PFIC type 1, 2, or 3; and
3. Member is 3 months of age or older; and
4. Member is experiencing both of the following:
    1. Moderate to severe pruritus; and
    2. Serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory; and
5. Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6mg; and
6. Prescribed by or in consultation with a hepatologist or gastroenterologist; and
7. Inadequate response or inability to tolerate at least TWO of the following treatments used for the relief of pruritus:
    1. Ursodeoxycholic acid (e.g., Ursodiol)
    2. Antihistamines (e.g., diphenhydramine, hydroxyzine)
    3. Rifampin
    4. Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Odevixibat (Bylvay™) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response to therapy (e.g., improvement in pruritus symptoms, reduced serum bile acids); and
2. Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6mg

Reauthorization duration: 2 years

Alagille Syndrome (ALGS)

INITIAL CRITERIA: Odevixibat (Bylvay™) is medically necessary when ALL of the following are met:

1. Diagnosis of Alagille Syndrome (ALGS); and
2. Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene; and
3. Member is experiencing both of the following:
    a. Moderate to severe pruritus; and
    b. Serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory; and
4. Inadequate response or inability to tolerate at least TWO of the following treatments used for the relief of pruritus:
    a. Ursodeoxycholic acid (e.g., Ursodiol)
    b. Antihistamines (e.g., diphenhydramine, hydroxyzine)
    c. Rifampin
    d. Bile acid sequestrants (e.g., cholestyramine, colestipol, colesevelam); and
5. Member is 12 months of age or older; and
6. Prescribed by or in consultation with a hepatologist or gastroenterologist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Odevixibat (Bylvay™) is medically necessary when there is documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score)

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Off-Label Uses Criteria**
Drugs	**Medications with off-label uses**
Covered Uses	Off-label uses: Medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria Revision/Review Date 2/2026	**Authorization:** 1. One of the following: a. Patient has had a documented trial and or intolerance with up to two preferred medications used to treat the documented diagnosis, or for medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. b. No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia **AND** 2. One of the following: a. Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Covered Uses section above) b. Requested use can be supported by at least two published peer reviewed clinical studies **AND** 3. Medication is being requested at an appropriate dose per literature **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Ohtuvayre**
Drugs	Ohtuvayre (ensifentrine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Primary diagnosis of asthma • Concomitant use of oral PDE4 inhibitors
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Ohtuvayre must be prescribed by or in consultation with a pulmonologist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for a 6 month duration and reauthorization requests will be approved for up to a 12 month duration
Other Criteria Revision/Review Date: 2/2026	**Initial Authorization:** • Diagnosis of chronic obstructive pulmonary disease (COPD) • Documentation of a pre- and post-albuterol FEV1/FVC ratio of <0.70 • Documented of a score of ≥ 2 on the Modified Medical Research Council (mMRC) Dyspnea Scale or a score of ≥ 10 on the COPD Assessment Test (CAT) • Documented trial, intolerance, or contraindication to treatment with a long-acting beta-2 agonist (LABA) plus a long-acting muscarinic antagonist (LAMA) (or a documented medical reason must be provided why the member is unable to use these therapies) • The drug is being prescribed at an FDA approved dose **Re-Authorization:** • The drug is being prescribed at an FDA approved dose • Documentation of clinical benefit from the medication (e.g. improvement in symptoms and exacerbations, improvement in mMRC or CAT, improvement in FEV1/FVC ratio, etc.) **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Ogsiveo®	nirogacestat
Truqap™	capivasertib
Lazcluze™	lazertinib
Itovebi™	inavolisib
Revuforj	revumenib

Policy:

A. Oncology agents are medically necessary when ONE of the following is met:

1. Drug is FDA approved for indication and regimen requested, including confirmation by genetic and/or biomarker testing when appropriate; or
2. The indication and regimen are classified as Category 1 or 2A by National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium™; or
3. The narrative text in American Hospital Formulary Service--Drug Information (AHFS-DI®) is supportive of the use; or
4. The indication is classified as Class I or Class IIa in Micromedex®

B. Ibrance®, Imbruvica® 140mg, 280mg tablet, Yonsa® or Zytiga® is medically necessary when BOTH of the following are met:

1. One of the following:
    a. Drug is FDA approved for indication and regimen requested, including confirmation by genetic and/or biomarker testing when appropriate; or
    b. The indication and regimen are classified as Category 1 or 2A by National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium™; or
    c. The narrative text in American Hospital Formulary Service—Drug Information (AHFS-DI®) is supportive of the use; or
    d. The indication is classified as Class I or Class IIa in Micromedex®; and
2. ONE of the following:
    a. For Brand Yonsa® only; ,: inadequate response or inability to tolerate Xtandi®; or
    b. For Brand Zytiga® only: inadequate response or inability to tolerate Xtandi® or Erleada®; or
    c. For Brand Ibrance® only, inadequate response or inability to tolerate Kisqali® and Verzenio®; or

d. For Imbruvica® 140mg, 280mg tablet only, inadequate response or inability to tolerate Imbruvica® 140mg capsule; or

e. For Brand Yonsa®, Brand Zytiga®, Brand Ibrance®, Imbruvica®140mg, 280mg tablet only, request is for continuation of therapy

Authorization duration: 2 years

P&T Approval Date: Mar-20-2025

Field Name	Field Description
Prior Authorization Group	**Oncology Drugs/Therapies**
Drugs	Oral and Injectable Oncology Medications (specialty or non-specialty) without product specific criteria when requested for an oncology diagnosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is an oncologist, or specialist in type of cancer being treated
Coverage Duration	If the criteria are met, the request will be approved for up to 6 month duration.
Other Criteria	**All of the following criteria must be met:** • Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) • Documentation has been provided of the results of all required genetic testing where required per product package insert • Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per product package insert • The product is being prescribed at a dose that is within FDA approved/NCCN guidelines. • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: o The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member's condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid

Revision/Review 11/2025	these drugs. The MedWatch form must be included with the prior authorization request ○ The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic product being requested Form FDA 3500 – Voluntary Reporting • **If the request is for abiraterone (Zytiga) 500 mg tablet, a documented medical reason why two tablets of generic abiraterone acetate 250 mg cannot be used** In accordance with the Commonwealth of Pennsylvania's Act 6 of 2020 c Fair Access to Cancer Treatment Act, individuals with stage four, advanced metastatic cancer will not be required to first fail to successfully respond to a different drug or biologic, or prove a history of failure in use of a different drug, before coverage for a covered drug is provided when both of the following apply: • The drug or biologic is approved by the US Food and Drug Administration (FDA) for the indication AND • The prescription of the drug or biologic is consistent with the best clinical practices for the treatment of stage four, advanced metastatic cancer or a severe adverse health condition experienced as a result of stage four, advanced metastatic cancer, and is supported by peer-reviewed medical literature. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Title: Onychomycosis agents

Applicable Drugs:

Brand Name	Generic Name
Jublia®	Efinaconazole
N/A	Tavaborole
Ciclodan®	Ciclopirox

Policy:

Efinaconazole (Jublia®), tavaborole (Kerydin®), or ciclopirox (Ciclodan®) 8% topical solution is medically necessary when ALL of the following are met:

1. Diagnosis of onychomycosis confirmed by one of the following:
    a. Positive potassium hydroxide (KOH) preparation; or
    b. Culture; or
    c. Histology and
2. The member does not have dermatophytomas or lunula (matrix) involvement; and
3. Inadequate response or inability to tolerate BOTH of the following:
    a. oral generic terbinafine; and
    b. oral generic itraconazole OR topical generic ciclopirox; and
4. One of the following:
    a. For efinaconazole (Jublia®) and tavaborole (Kerydin®) only, member is 6 years of age or older; or
    b. For ciclopirox (Ciclodan®) 8% topical solution only, member is 12 years of age or older

Authorization duration: 1 year

P&T Approval Date: 11/2025

Title: Opioids

Policy:

PRIOR AUTHORIZATION

I. Transmucosal Immediate Release Fentanyl (TIRF) Product fentanyl citrate is considered medically necessary when:
A. INITIAL CRITERIA [Authorization duration: 1 year]: Transmucosal Immediate Release Fentanyl (TIRF) Products are considered medically necessary when there is documentation of ALL of the following:

1. **Use for breakthrough pain associated with active cancer treatment or cancer not in remission in members who are receiving long-acting opioid therapy; and**

2. **Member is 18 years of age or older (16 years of age and older for fentanyl citrate); and**

3. **Member is tolerant to current opioid therapy (i.e., adherence to one of the following regimens for one week or longer: 25mcg of transdermal fentanyl hourly, 30mg of oxycodone daily, 60mg of oral morphine daily, 8mg of oral hydromorphone daily, 25mg of oral oxymorphone daily; or an equianalgesic dose of another opioid)**

B. REAUTHORIZATION CRITERIA [Authorization duration: 1 year]: Transmucosal Immediate Release Fentanyl (TIRF) product is re-approved when there is documentation of continued use for breakthrough pain associated with active cancer treatment or cancer not in remission in members who are currently receiving long-acting opioid therapy
II. Opioid regimens containing greater than 90 morphine milligram equivalents per day, long acting opioids, and short acting opioids for continuation beyond 30 days [Authorization duration: 1 year] - are considered medically necessary as follows:

A. INITIAL CRITERIA: The requested product or regimen is considered medically necessary when there is ONE of the following:
1. Pain associated with active cancer treatment, cancer not in remission, or sickle cell anemia (regardless of age); OR
2. Severe, persistent chronic pain with documentation of diagnosis associated with pain and ALL of the following:

1. **Documentation of a current patient-prescriber opioid treatment agreement (signed within one year of request); and**

2. **ONE of the following**

1. **Documentation of a current patient-prescriber opioid treatment agreement (signed within one year of request); and**
2. **documentation that a urine drug screen (UDS) will be performed by prescriber within 1 year of request.**

III. Appropriate Utilization with Medication Assistant Treatments (MAT) for opioid use disorder - [Authorization duration: 2 months] - Opioid analgesics will require prior authorization for medical necessity when filled within two months of a paid claim for either buprenorphine/naloxone (Suboxone®/Zubsolv®) or buprenorphine sublingual tablet. Opioid analgesic products are approved in patients that have received buprenorphine/naloxone or buprenorphine in the previous two months when there is documentation of a treatment plan showing discontinuation of buprenorphine containing MAT.

DAYS' SUPPLY AND QUANTITY LIMITS

I. Day supply limit Criteria
A. Short-acting opioids for short term use (greater than two 5-day fills within 60 days for 18 and older, and greater than two 3-day fills within 60 days for age less than 18) [Authorization duration: 1 month for a 30 days' supply] - an exception is approved when ALL of the following are met:
INITIAL CRITERIA

1. **Diagnosis of acute pain; and**
2. **Prescriber reviewed member's history in state Prescription Drug Monitoring Program website; and**
3. **Prescriber counseled member (or member's representative) on risk of addiction; and**
4. **Substance abuse screening done by prescriber**

REAUTHORIZATION CRITERIA see Opioid regimens containing greater than 90 morphine milligram equivalents per day, long acting opioids, and short acting low dose opioids for continuation beyond additional 30 days Prior Authorization criteria under section under section II.A above

B. Opioid containing cough and cold products are limited to two five (5) day fills within 60 days for 18 and older and two 3-day fills within 60 days for age less than 18 - an exception is approved when
INITIAL CRITERIA: there is documentation of inadequate response or inability to tolerate non-opioid therapies for the indication [Authorization duration 1 month]

REAUTHORIZATION CRITERIA: Documentation the underlying etiology of cough has been identified and treated, if applicable (e.g,, allergic rhinitis, asthma, GERD) [Authorization duration 6 months]

C. Butalbital containing headache products are limited to one five (5) day fill within 30 days. Opioid containing headache products are limited to one three (3) day fill within 30 days for less than 18 years of age, an exception is approved as follows:

INITIAL CRITERIA [Authorization duration: 3 months]: All of the following:

1. **Diagnosis of one of the following:**
    1. **Tension-type or muscular headache**
    2. **Migraine headache**
2. **Member is 12 years of age or older**
3. **Inadequate response or inability to tolerate TWO of the following:**
    1. **At least two triptans**
    2. **Non-steroid anti-inflammatory drugs (e.g., ibuprofen, naproxen)**
    3. **Neuroleptics (e.g., prochlorperazine, metoclopramide)**
    4. **Dihydroergotamine**

REAUTHORIZATION CRITERIA: [Authorization duration: 1 year]: All of the following:

1. **Diagnosis of one of the following:**
    1. **Tension-type or muscular headache**
    2. **Migraine headache**
2. **Member is 12 years of age or older**
3. **Prescribed by or in consultation with a neurologist or a headache specialist, or pain specialist**
4. **Inadequate response or inability to tolerate NSAIDs**
5. **Ongoing assessment of medication-overuse headache**

II. Quantity limit Criteria –
A. Opioid pain products [authorization duration = 1 year] An increased quantity of an opioid medication is approved when there is documentation of ALL of the following:

1. **Current patient-prescriber opioid treatment agreement (signed within one year of request); and**
2. **The requested dose and frequency do not exceed FDA approved dosing or are supported by compendia; and**
3. **ONE of the following:**
    1. **The dose cannot be achieved with commercially available clinical dosage forms; or**
    2. **Documentation indicating medical necessity for a quantity that exceeds the plan limit (e.g. GI malabsorption).**

B. Cough and cold products [Authorization duration: 1 month for initial; 6 months for reauthorizations] - An increased quantity of an opioid containing cough and cold medication is approved when there is documentation of ALL of the following:

1. **The requested dose and frequency do not exceed FDA approved dosing or are supported by compendia; and**
2. **Documentation of diagnosis requiring long-term therapy with requested cough/ cold medications; and**
3. **Inadequate response or inability to tolerate non-opioid therapies for the indication**

C. Butalbital containing headache products [Authorization duration:1 year] - An increased quantity of a butalbital containing headache medication is approved when there is documentation of ALL of the following:

1. **The requested dose and frequency do not exceed FDA approved dosing or are supported by compendia; and**
2. **Inadequate response or inability to tolerate prophylactic therapy; and**
3. **Prescribed by or in consultation with a neurologist, headache specialist or pain specialist.**

D. Buprenorphine/ naloxone (Suboxone®/Zubsolv®) and buprenorphine sublingual tablet [Authorization duration: 6 months]: buprenorphine/ naloxone or buprenorphine for the treatment of opioid use disorder are approved in quantities greater than those specified in the policy when ALL of the following are met:

1. **The requested dose and frequency do not exceed FDA approved dosing or are supported by compendia; and**

2. **The dose cannot be achieved with commercially available dosage forms; and**
3. **Inadequate response to lower doses**

All products containing the active ingredients in the chart below are subject to the following:

- **Opioid regimens containing greater than 90 morphine milligram equivalents per day**
- **Appropriate Utilization with Medication Assistant Treatments (MAT) for opioid use disorder**

Active ingredient
Benzhydrocodone
Codeine
Dihydrocodeine
Fentanyl
Hydrocodone
Hydromorphone
Levorphanol
Meperidine
Methadone
Morphine
Opium
Oxycodone
Oxymorphone
Tapentadol

Tramadol

The table below identifies medications that are found in the following sections of this policy:

- **Transmucosal Immediate Release Fentanyl (TIRF) Products (¥ identifies impacted medications)**
- **Opioid regimens containing greater than 90 morphine milligram equivalents per day, long acting opioids, and short acting low dose opioids for continuation beyond 30days (*identifies impacted long acting opioids)**
- **Days' Supply and Quantity Limits**

Drug Name	Days' Supply Limit	Maximum Quantity per Day	Quantity limit per rolling 30 days, unless otherwise specified (tablet, capsule)
Acetaminophen/codeine #2 300/15mg tab	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	12	
Acetaminophen/codeine #3 300/30mg tab	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	12	

Acetaminophen/codeine #4 300/60mg tab	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Acetaminophen/codeine liquid	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	90mL	
Benzhydrocodone/acetaminophen (Apadaz®)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	12	
Buprenorphine film* (Belbuca®)	No	2	
Buprenorphine patch* (Butrans®)	No		4 patches
Buprenorphine sublingual tablet 2mg	No	4	
Buprenorphine sublingual tablet 8mg	No	3	
Buprenorphine/naloxone (Suboxone® 2/0.5mg, 4/1mg)	No	4	

Buprenorphine/ naloxone (Suboxone® 8/2mg)	No	3	
Buprenorphine/ naloxone (Suboxone® 12/3mg)	No	2	
Buprenorphine/naloxone (Zubsolv® 1.4/0.36mg, 2.9-0.71mg)	No	4	
Buprenorphine/naloxone (Zubsolv® 5.7/1.4mg, 0.7/0.18mg)	No	3	
Buprenorphine/naloxone (Zubsolv® 8.6/2.1mg)	No	2	
Buprenorphine/naloxone (Zubsolv® 11.4-2.9mg)	No	1	
Buprenorphine/naloxone 2.1/0.3mg	No	4	
Buprenorphine/naloxone 4.2/0.7mg	No	3	
Buprenorphine/naloxone 6.3/1mg	No	1	
Butalbital/apap (Allzital®)	one 5-day fill per 30 days	6	
Butalbital/apap/caffeine without codeine (Esgic®, Fioricet®)	one 5-day fill per 30 days	6	
Butalbital/apap/caffeine with codeine (Esgic®, Fioricet®/codeine)	one 5-day fill per 30 days for 18 and over; one 3-day fill per 30 days for less than 18	6	

Butalbital/asa/caffeine without codeine	one 5-day fill per 30 days	6	
Butalbital/asa/caffeine with codeine	one 5-day fill per 30 days for 18 and over; one 3-day fill per 30 days for less than 18	6	
Carisoprodol/ aspirin/ codeine	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	8	
Codeine sulfate tablets 15mg, 30mg	two 5-day fills per 60 for 18 and older; two 3-day fills per 60 days for less than 18	12	
Codeine sulfate tablets 60mg	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	

Codeine/chlorpheniramine (Tuxarin® ER)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	2	
Codeine/chlorpheniramine tablets	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	20mL	
Codeine/ chlorpheniramine solution	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	60mL	
Dihydrocodeine/ acetaminophen/ caffeine (Trezix®)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	10	
Fentanyl IR¥ (Actiq®, Fentora®)	No	4	
Fentanyl nasal solution¥	No	1	

Fentanyl patch*	No		15 patches
Guaifenesin/ codeine (Coditussin® AC)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	60mL	
Guaifenesin/ codeine (MAR-COF® CG)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	45mL	
Guaifenesin/ codeine	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	90mL	
Hydrocodone bitartrate ER* (Hysingla® ER)	No	1	
Hydrocodone bitartrate ER*	No	2	
Hydrocodone/acetaminophen 2.5/325mg, 5/300mg,7.5/300mg, 5/325mg, 7.5/325mg tab (Xodol®)	two 5-day fills per 60 days for 18 and older; two 3-day	12	

	fills per 60 days for less than 18		
Hydrocodone/apap 10/325mg, 10/300mg tab (Xodol®)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Hydrocodone/apap liquid (10mg/325mg/15ml, 2.5mg/167mg/5ml, 5mg/333mg/10ml, 7.5mg/325mg/15ml, 10mg/300mg/15ml)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	90mL	
Hydrocodone/chlorpheniramine	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	10mL	
Hydrocodone/chlorpheniramine	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	2	

Hydrocodone/ homatropine (Hydromet®)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	30mL	
Hydrocodone/ homatropine	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Hydrocodone/ibuprofen	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	5	
Hydromorphone (Dilaudid®)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Hydromorphone 1mg/1ml liquid (Dilaudid®)	two 5-day fills per 60 days for 18	12mL	

	and older; two 3-day fills per 60 days for less than 18		
Hydromorphone extended release* (Exalgo®)	No	2	
Levorphanol tartrate 2mg	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Levorphanol tartrate 3mg	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	4	
Meperidine 50mg/5ml liquid	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	67mL	
Meperidine HCL (Demerol®)	two 5-day fills per 60 days for 18	6	

	and older; two 3-day fills per 60 days for less than 18		
Methadone* tabs 5mg, 10mg	No	6	
Methadone solution* 5mg/5ml	No	60mL	
Methadone solution* 10mg/5ml	No	30mL	
Methadone solution* (Methadose concentrate, Methadose sugar-free concentrate) 10mg/1ml	No	6mL	
Morphine 10mg/5ml liquid	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	45 mL	
Morphine 20mg/5ml liquid	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	23 mL	
Morphine concentrate 20mg/1ml, 10mg/0.5ml, 5mg/0.25ml liquid	two 5-day fills per 60 days for 18 and older;	6mL	

	two 3-day fills per 60 days for less than 18		
Morphine sulfate IR (MSIR®)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Morphine sulfate ER capsules*	No	1	
Morphine sulfate ER capsules*	No	2	
Morphine sulfate SR*	No	3	
Morphine sulfate SR* (MS Contin®)	No	3	
Morphine sulfate/naltrexone*	No	2	
Morphine suppositories 5mg	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	18	
Morphine suppositories 10mg	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60	6	

	days for less than 18		
Morphine suppositories 20mg, 30mg	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Opium tincture	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	N/A	
Oxycodone 7.5mg tab (Oxaydo®)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	8	
Oxycodone HCL (Oxy® IR/Roxicodone®/Oxaydo®, Roxybond®) 5mg caps/tabs	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	12	

Oxycodone HCL (Oxy® IR/Roxicodone®, Roxybond®), 10mg, 15 mg, 30mg caps/tabs	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Oxycodone 5mg/5ml liquid	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	60 mL	
Oxycodone highly concentrated liquid 20mg/1ml liquid	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6mL	
Oxycodone HCL ER* (Oxycontin®)	No	3	
Oxycodone ER* (Xtampza® ER)	No	2	
Oxycodone/Acetaminophen, Endocet® (Percocet®, Nalocet®, Prolate®) 2.5/325mg tab, 2.5/300mg tab, 5/300mg, 5/325mg tab	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	12	

Oxycodone/Acetaminophen (Prolate®) 7.5/300mg tab, 10/300mg tab	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Oxycodone/acetaminophen 7.5/325mg tab (Endocet®/Percocet®)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	8	
Oxycodone/acetaminophen 10/325mg tab (Endocet®/Percocet®)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Oxycodone/acetaminophen 5mg/325mg/5ml liquid	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	60	

Oxycodone/aspirin 4.8355/325mg tab	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	12	
Oxycodone/Acetaminophen (Prolate®) 10-300mg/5ml soln	Two 5-days fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	30 ml	
Oxymorphone HCL	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Oxymorphone HCL ER*	No	3	
Phenylephrine/ brompheniramine/ codeine	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	90mL	

Phenylephrine/ chlorpheniramine/ codeine (Capcof®)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	60mL	
Phenylephrine/ dexchlorpheniramine/ codeine (Pro-red® AC)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	60mL	
Promethazine/codeine 6.25-10mg/5mL syrup	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	30mL	
Pseudoephedrine/ brompheniramine/ codeine (MAR-COF® BP)	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	60mL	
Pseudoephedrine/codeine/ guaifenesin solution 30-10-100 MG/5ML	two 5-day fills per 60 days for 18	40mL	

	and older; two 3-day fills per 60 days for less than 18		
Pseudoephedrine/ dexbrompheniramine/ codeine	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	60mL	
Tapentadol (Nucynta®) 50mg	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	4	
Tapentadol (Nucynta®) 75mg, 100mg	two 5-day fills per 60 days for 18 and older; two 3-day fills per 60 days for less than 18	6	
Tapentadol ER* (Nucynta® ER)	No	2	
Tramadol 50mg, 25mg		8	
Tramadol 75mg		5	
Tramadol (Conzip®)		1	

Tramadol/acetaminophen		8	
Tramadol/celecoxib (Seglentis®)	No	4	
Tramadol 100 mg		4	
Tramadol (Qdolo®)		80ml	

P&T Approval Date: 2/2026

Title: Oral Anti-infective Agents

Applicable Drugs:

Brand Name	Generic Name
Cresemba®	isavuconazonium
Sirturo®	bedaquiline
Sivextro®	tedizolid
	Pretomanid
Nuzyra®	omadacycline

Policy:

BEDAQUILINE (SIRTURO®)

Bedaquiline (Sirturo®) is approved when ALL of the following are met:

1. Diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB), for which an effective treatment regimen cannot otherwise be established; and
2. Member is 2 years of age or older and weighing at least 8 kg; and
3. Prescribed by or in consultation with an infection disease specialist or pulmonologist; and
4. Bedaquiline is used as combination therapy as defined by ONE of the following:
    a. With at least 3 other drugs to which the member's MDR-TB isolate has been shown to be susceptible in vitro; or
    b. With at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible

Authorization duration: 24 weeks

ISAVUCONAZONIUM (CRESEMBA®)

Isavuconazonium (Cresemba®) is approved when ALL of the following are met:

1. Prescribed by or in consultation with an infectious disease specialist; and
2. Diagnosis of ONE of the following:
    a. Treatment of invasive aspergillosis and inadequate response or inability to tolerate voriconazole; or
    b. Treatment of invasive mucormycosis

Authorization duration: 12 months

TEDIZOLID (SIVEXTRO®)

Tedizolid (Sivextro®) is approved when ALL of the following are met:

1. Prescribed by or in consultation with an infectious disease specialist; and
2. Documentation of use for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of Gram-positive microorganisms and ONE of the following:
    a. Inadequate response or inability to tolerate ALL antibiotics to which the organism is susceptible; or
    b. Tedizolid is the only antibiotic to which the organism is susceptible; or
    c. There is a contraindication to using an alternative antibiotic to which the organism is susceptible to (e.g., drug-drug interaction concern with the alternative antibiotic and member's existing drug regimen)

Authorization duration: 4 weeks

PRETOMANID

Pretomanid is approved when ALL of the following are met:

1. Diagnosis of pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB); and

2. Medication will be used as part of combination regiment with bedaquiline (Sirturo®) and linezolid; and
3. Member is 18 years of age or older; and
4. Prescribed by or in consultation with an infectious disease specialist

Authorization duration: 26 weeks

OMADACYCLINE (NUZYRA®)

Omadacycline (Nuzyra®) is approved when ALL of the following are met:

1. Member is 18 years of age or older; and
2. Prescribed by or in consultation with an infectious disease specialist; and
3. One of the following:
    a. Documentation of use for the treatment of community-acquired bacterial pneumonia; or
    b. Documentation of use for the treatment of acute bacterial skin and skin structure infections (ABSSSI); and
4. ONE of the following:
    a. Inadequate response or inability to tolerate ALL antibiotics to which the organism is susceptible; or
    b. Omadacycline is the only antibiotic to which the organism is susceptible; or
    c. There is a contraindication to using an alternative antibiotic to which the organism is susceptible to (e.g., drug-drug interaction concern with the alternative antibiotic and member's existing drug regimen)

Authorization duration: 4 weeks

P&T Approval Date: 11/2025

Title: Oteseconazole (Vivjoa)

Applicable Drugs:

Brand Name	Generic Name
Vivjoa	oteseconazole

Policy:

INITIAL CRITERIA: Oteseconazole (Vivjoa™) is approved when ALL of the following are met:

1. Diagnosis of recurrent vulvovaginal candidiasis (RVVC); and
2. Member is not of reproductive potential; and
3. Diagnosis of RVVC is confirmed by ONE of the following:
    a. Positive potassium hydroxide (KOH) preparation; or
    b. Vaginal fungal culture; and
4. Member has experienced 3 or more symptomatic episodes of vulvovaginal candidiasis (VVC) within the past 12 months; and
5. Inadequate response or inability to tolerate BOTH of the following:
    a. One intravaginal product (e.g., clotrimazole, miconazole, terconazole); and
    b. Oral fluconazole

Authorization duration: 4 months

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Oxervate**
Drugs	Oxervate (cenegermin-bkbj)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an ophthalmologist or optometrist
Coverage Duration	If all of the criteria are met, the request will be approved for a one-time 8-week treatment course. Additional treatment beyond 8-weeks will not be authorized.
Other Criteria	• Documented diagnosis of Stage 2 or 3 neurotrophic keratitis • Documented treatment failure with at least one conventional non-surgical treatment for neurotrophic keratitis (i.e., artificial tear products, therapeutic soft contact lenses)
Revision/Review Date 11/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Oxymetazoline (Upneeq™)

Applicable Drugs:

Brand Name	Generic Name
Upneeq™	Oxymetazoline hydrochloride

Policy:

INITAL CRITERIA: Oxymetazoline (Upneeq™) is approved when ALL of the following are met:

1. Diagnosis of acquired blepharoptosis; and
2. Request is not for an excluded benefit (i.e. cosmetic - solely for lifting the eyelid to improve appearance); and
3. Member has obstructed visual field in primary gaze or down gaze due to blepharoptosis; and
4. One of the following:
    a. Marginal reflex distance-1 (MRD-1) is less than or equal to 2mm in primary gaze; or
    b. Marginal reflex distance-1 (MRD-1) is less than or equal to 2mm in down gaze; or
    c. Superior visual field loss of at least 12 degrees or 24 percent; and
5. Other treatable causes of blepharoptosis have been ruled out (e.g., recent botulinum toxin injection, myasthenia gravis); and
6. Prescribed by or in consultation with an ophthalmologist or optometrist

Initial authorization duration: 3 months

REAUTHORIZATION CRITERIA: Oxymetazoline (Upneeq™) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy (e.g., improvement in superior visual field, increase in Marginal reflex distance-1 [MRD-1]); and
2. One of the following:

a. Marginal reflex distance-1 (MRD-1) is less than or equal to 2mm in primary gaze; or

b. Marginal reflex distance-1 (MRD-1) is less than or equal to 2mm in down gaze; or

c. Superior visual field loss of at least 12 degrees or 24 percent

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Title: Palopegteriparatide (Yorvipath®)

Applicable Drugs:

Brand Name	Generic Name
Yorvipath®	palopegteriparatide

Policy:

INITIAL CRITERIA: Palopegteriparatide (Yorvipath®) is medically necessary when ALL of the following are met:

1. Diagnosis of hypoparathyroidism; and
2. Requested drug is not being used in the setting of acute post-surgical hypoparathyroidism; and
3. Member has achieved albumin-corrected serum calcium of at least 7.8 mg/dL using calcium and active vitamin D (e.g., calcitriol) treatment; and
4. Prescribed by or in consultation with an endocrinologist or nephrologist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Palopegteriparatide (Yorvipath®) medically necessary when there is documentation of positive clinical response to therapy as evidenced by maintenance of normalized calcium levels compared to baseline

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	Palsonify (paltusotine)
Drugs	Palsonify (paltusotine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in conjunction with an endocrinologist
Coverage Duration	If all the criteria are met, the initial and reauthorization requests will be approved for 12 months.
Other Criteria Date: 05/2026	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Member has a diagnosis of acromegaly • Member has had inadequate response to surgery or medical reason why surgery is not an option • Member has had an inadequate response to therapy with an injectable somatostatin analog, or has a documented medical reason why an injectable somatostatin analog cannot be used • Clinical justification is provided as to why member cannot continue use of injectable somatostatin analog therapy **Re-Authorization:** • Documentation has been provided that demonstrates a clinical benefit (e.g., improvement in laboratory values, improvement or stabilization of clinical signs/symptoms, etc.) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Papzimeos**
Drugs	Papzimeos (zopapogene imadenovec)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with a pulmonologist, otolaryngologist, oncologist, or other specialist in the treatment of recurrent respiratory papillomatosis
Coverage Duration	If the criteria are met, the request will be approved for up to a 12-week course of therapy. **Renewal requests or requests for more than a one-time course of therapy will not be approved.**
Other Criteria Revision/Review Date: 11/2025	**Initiation of Therapy:** • Member has a diagnosis of recurrent respiratory papillomatosis • Documentation is provided confirming human papilloma type 6 or 11 • Member has a history of voice or airway symptoms which have required 3 or more clinically indicated interventions (surgical resection or laser ablation of disease) in the previous 12 months **Renewal Requests:** Renewal requests or requests for more than a one-time course of therapy will not be approved. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Peanut immunotherapy (Palforzia)

Applicable Drugs:

Brand Name	Generic Name
Palforzia®	Peanut immunotherapy

Policy:

INITIAL CRITERIA Peanut immunotherapy (Palforzia®) is medically necessary when ALL of the following are met:

1. Diagnosis of peanut allergy as documented by all of the following:
    a. Serum peanut-specific IgE level of greater than or equal to 0.35kUA/L; and
    b. Mean wheal diameter that is at least 3mm larger than the negative control on skin-prick testing for peanut; and
2. Member does not have any of the following:
    a. History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease; or
    b. History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months; or
    c. Severe or poorly controlled asthma; and
3. One of the following:
    a. Member is 1 to 17 years of age and in the initial dose escalation phase of therapy; or
    b. Member is 1 years of age or older and in the up-dosing or maintenance phase of therapy; and
4. Prescribed by or in consultation with an allergist/immunologist

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Peanut immunotherapy (Palforzia®) is medically necessary when prescribed by or in consultation with allergist/immunologist.

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Title: Peginterferon alfa-2a (Pegasys®)

Applicable Drugs:

Brand Name	Generic Name
Pegasys	peginterferon alfa-2a

Policy:

Chronic Hepatitis C (CHC)

INITIAL CRITERIA: Peginterferon alfa-2a (Pegasys®) is approved when ALL of the following are met:

1. Diagnosis of Chronic Hepatis C (CHC); and
2. Member is without decompensated liver disease (defined as Child-Pugh Class B or C); and
3. One of the following:
    1. Used in combination with one of the following:
        1. Sovaldi (sofosbuvir); or
        2. Ribavirin; or
    2. Inadequate response or inability to tolerate all other HCV agents (e.g., Sovaldi (sofosbuvir), ribavirin); and
4. Prescribed by or in consultation with one of the following:
    1. Hepatologist
    2. Gastroenterologist
    3. Infectious disease specialist
    4. HIV specialist certified through the American Academy of HIV medicine

Initial authorization duration: 28 weeks

REAUTHORIZATION CRITERIA: Peginterferon alfa-2a (Pegasys®) is re-approved when ALL of the following are met:

1. Member has an undetectable HCV RNA at week 24; and

2. Additional treatment weeks of peginterferon are required to complete treatment regimen; and
3. Member has not exceeded 48 weeks of therapy with peginterferon; and
4. Prescribed by or in consultation with one of the following:
    1. Hepatologist
    2. Gastroenterologist
    3. Infection disease specialist
    4. HIV specialist certified through the American Academy of HIV medicine

Reauthorization duration: 20 weeks

Chronic Hepatitis B (CHB)

Peginterferon alfa-2a (Pegasys®) is approved when BOTH of the following are met:

1. Diagnosis of chronic hepatitis B infection; and
2. Member is without decompensated liver disease (defined as Child-Pugh Class B or C)

Authorization duration: 48 weeks

P&T Approval Date: 11/2025

Title: Pegvaliase-pqpz (Palynziq™)

Applicable Drugs:

Brand Name	Generic Name
Palynziq™	Pegvaliase-pqpz

Policy:

INITIAL CRITERIA: Pegvaliase-pqpz (Palynziq™) is medically necessary when ALL of the following are met:

1. Member is 18 years of age or older, and
2. Member has diagnosis of phenylketonuria with uncontrolled blood phenylalanine concentration of greater than 600 micromol/L on existing management (e.g., medical foods, Kuvan®); and
3. Member will continue to have phenylalanine blood levels measured every 4 weeks until a maintainance dose is established and periodically thereafter; and
4. ONE of the following:
    1. Member has had an inadequate response or inability to tolerate the generic sapropterin; or
    2. Member is not a candidate for generic sapropterin therapy due to the presence of two null mutations in trans

Initial Authorization duration: 6 months

CONTINUATION CRITERIA: Pegvaliase-pqpz (Palynziq™) is medically necessary when there is documentation of a positive clinical response to Pegvaliase-pqpz (Palynziq™) therapy (i.e., reduction in blood phenylalanine concentrations).

Continuation authorization duration: 2 years

P&T Approval Date: 11/2025

Title: Pegvisomant (Somavert®)

Applicable Drugs:

Brand Name	Generic Name
Somavert®	Pegvisomant

Policy:

INITIAL CRITERIA: Pegvisomant (Somavert®) is medically necessary when ALL the following are met:

1. Diagnosis of acromegaly; and
2. One of the following:
    a. Inadequate response to surgery or pituitary irradiation; or
    b. Not a candidate for surgical resection or pituitary irradiation; and
3. Inadequate response or inability to tolerate a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses; and
4. Prescribed by or in consultation with an endocrinologist; and
5. Member is 18 years of age or older

Initial authorization duration: 12 months

REAUTHORIZATION CRITERA: Pegvisomant (Somavert®) is medically necessary when there is documentation of positive clinical response to Somavert® therapy (i.e., reduction or normalization of IGF-1)

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Pentosan polysulfate (Elmiron)

Applicable Drugs:

Brand Name	Generic Name
Elmiron®	pentosan polysulfate sodium

Policy:

INITIAL CRITERIA: Pentosan polysulfate sodium (Elmiron®) is medically necessary when ALL of the following are met:

1. Diagnosis of interstitial cystitis/ bladder pain syndrome and BOTH of the following:
    a. Pain, pressure, or discomfort associated with lower urinary tract symptoms for 6 weeks or longer; and
    b. Absence of infection or other identifiable cause; and
2. Inadequate response to conservative therapy (e.g., bladder training, pelvic floor rehab, biofeedback, etc.); and
3. Member is 16 years of age or older; and
4. Inadequate response or inability to tolerate ONE of the following:
    a. Amitriptyline; or
    b. Cimetidine; or
    c. Hydroxyzine

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Pentosan polysulfate sodium (Elmiron®) is medically necessary when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Phenoxybenzamine (Dibenzyline®)

Applicable Drugs:

Brand name	Generic name
Dibenzyline®	phenoxybenzamine

Policy:

INITIAL CRITERIA: Phenoxybenzamine (Dibenzyline®) is medically necessary when ALL of the following are met:

1. Diagnosis of pheochromocytoma; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a nephrologist, endocrinologist or endocrine surgeon; and
4. For brand Dibenzyline® only, inadequate response or inability to tolerate generic phenoxybenzamine; and
5. Medication is being used for preoperative preparation; and
6. Treatment will also include a high-sodium diet and fluid intake; and
7. Inadequate response or inability to tolerate to one of the following
    1. Doxazosin; or
    2. Terazosin; or
    3. Prazosin.

Initial Authorization duration: 6 months

REAUTHORIZATION CRITERIA: Phenoxybenzamine (Dibenzyline®) is medically necessary when both of the following are met:

1. Documentation of positive clinical response; and
2. Yearly evaluation by prescriber for long-term use

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Prior Authorization Group	**Phenylalanine Hydroxylase Activators**
Drug(s)	Formulary: Sapropterin dihydrochloride (Kuvan) Non-Formulary: Sephience (sepiapterin) Any other marketed agent within the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by specialist experienced in treating PKU
Coverage Duration	**Initial:** If all of the criteria are met, the request will be approved for up to 1 month. **Reauthorization:** If all of the criteria are met, sapropterin requests will be approved for a duration of 1 month for members who require a dose increase to 20 mg/kg/day due to non-responsiveness. Sephience requests will be approved for a duration of 1 month for patients who require a dose increase from their previous dose (up to a max dose of 60 mg/kg/day) due to non-responsiveness. For all other members the request will be approved for a duration of 3 months.
Other Criteria	**Initial Authorization:** • Documentation of a confirmed diagnosis of Phenylketonuria (PKU) • Documentation of the member's baseline blood Phe level. (within 30 days of the request) • Documentation consistent with order forms, receipts, or chart notes (within 30 days of request) that the member is currently utilizing a Phe-restricted diet • For Sephience: Documented trial and failure, intolerance, or contraindication to sapropterin in combination with Phe- restricted diet • Documentation of the member's current weight. • The medication is being prescribed at an FDA approved dosage **Reauthorization:** *For sapropterin: Members that were dosed at 20mg/kg/day and did not have a decrease in Phe from baseline, are considered NON-RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.* *For Sephience: Members that were dosed at 60 mg/kg/day and did not have a decrease in Phe from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.* • Documentation of the member's current weight.

Revision/Review Date: 11/2025	• Documentation of at least **two** separate blood Phe level results after initiation of therapy (within 30 days of request). • The medication is being prescribed at an FDA approved dosage. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Title: Pimavanserin (Nuplazid)

Applicable Drugs:

Brand Name	Generic Name
Nuplazid®	pimavanserin

Policy:

INITIAL CRITERIA: Pimavanserin (Nuplazid®) is medically necessary when ALL of the following are met:

1. Diagnosis of hallucinations and delusions associated with Parkinson's disease; and
2. Trial of dose adjustment or withdrawal of antiparkinsonian medications (anticholinergics, amantadine, dopamine agonists, COMT inhibitors, selegiline) prior to treatment with pimavanserin; and
3. Inadequate response or inability to tolerate clozapine or quetiapine; and
4. Member is 18 years of age or older

Initial Authorization duration: 6 months

REAUTHORIZATION CRITERIA: Pimavanserin (Nuplazid®) is medically necessary when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Presbyopia Agents**
Drugs	Vuity (pilocarpine HCl ophthalmic solution) Qlosi (pilocarpine HCl ophthalmic solution) Vizz (aceclidine ophthalmic solution)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Vuity: 40-55 years Qlosi: 45-64 years Vizz: 45-75 years
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 2/2026	**Initial Authorization:** • Diagnosis of presbyopia • Trial and failure or contraindication to corrective lenses (i.e., eye glasses, contact lenses) • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Prescription Drugs or Biologics With an Accelerated Approval

Policy:

Coverage is subject to the terms, conditions, and limitations of the member's contract.

Prescription drugs or biologics that receive an accelerated approval are considered a benefit contract exclusion for most plans, and, therefore, not eligible for reimbursement consideration for a period of 18 months following the US food and Drug Administration (FDA) accelerated approval date when ALL of the following are met:

1. The drug does not have a final, standard, traditional FDA approval, and
2. The accelerated approval was based on a surrogate endpoint, and
3. The FDA indicates that a confirmatory trial is necessary to demonstrate clinical benefits.

During the 18-month consideration period, the Company will evaluate any new reliable data. By the end of this consideration period of 18 months, the Company will provide a coverage position based on the current status of those reliable data.

This exclusion does not apply to prescription drugs or biologics under the following circumstances :

1. The prescription drugs or biologics are an anti-cancer treatment, or
2. Coverage is required based on a federal or state mandate/regulation.

Individual benefits must be verified.

NOTE: For plans that do not have a benefit contract exclusion for prescription drugs or biologics that receive an accelerated approval with insufficient reliable evidence of effectiveness, refer to the applicable medical necessity policies for additional information.

P&T Approval Date: Dec-12-2024

Title: Prescription Vitamins, Dietary Supplements, and Medical Foods

Policy:

Coverage is subject to the terms, conditions, and limitations of the member's contract.

Prescription vitamins, dietary supplements, and medical foods are not covered under the pharmacy benefit.

An exception to allow coverage under the member's plan will be in place for prescription medication that are either mandated when used as a preventive medication as described in the Patient Protection and Affordable Care Act (PPACA) or medically necessary for the treatment of a specific illness as determined by the plan.

The following prescription products are covered under the member's prescription benefit:

Products	**Clinical Use**
Calcitriol oral	Management of secondary hyperparathyroidism and resultant metabolic bone disease in patients with moderate to severe chronic renal failure (creatinine clearance 15 to 55 mL/min) not yet on dialysis.
Cholecalciferol (vitamin D3) 50,000 units	Treatment of hypoparathyroidism, refractory rickets, also known as vitamin D resistant rickets, and familial hypophosphatemia. This is an over the counter preparation included to meet essential health benefit requirements.
Cyanocobalamin inhaled	Maintenance of normal hematologic status in pernicious anemia patients who are in remission following intramuscular (IM) vitamin B12 therapy and who have no nervous system involvement
Dialysis vitamins oral as identified by indication in product label	Wasting syndrome in chronic renal failure, uremia, and impaired metabolic function of the kidney
Doxercalciferol oral	Secondary hyperparathyroidism (dialysis patients): Treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis. Secondary hyperparathyroidism (predialysis patients):

	Treatment of secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease.
Ergocalciferol oral	Treatment of hypoparathyroidism, refractory rickets, also known as vitamin D resistant rickets, and familial hypophosphatemia.
Paricalcitol oral	Hyperparathyroidism: For the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease stage 3 and 4, and chronic kidney disease stage 5 in patients on hemodialysis or peritoneal dialysis.
Pediatric vitamins	Nutritional supplement for children
Phytonadione oral	Anticoagulant-induced prothrombin deficiency caused by coumarin or indandione derivatives. Coagulation disorders: Phytonadione is indicated in the following coagulation disorders which are due to faulty formation of factors II, VII, IX and X when caused by vitamin K deficiency or interference with vitamin K activity.
Potassium aminobenzoate oral	The treatment of scleroderma, dermatomyositis, morphea, linear scleroderma, pemphigus, and Peyronie's disease.
Prenatal vitamins	Nutritional supplement used prior to conception, during pregnancy, and in the postnatal period
Prescription electrolytes	Electrolyte repleters (i.e., potassium) and electrolyte depleters (i.e., calcium acetate)

P&T Approval Date: Jul-01-2024

Title: Prior Authorization Requirement for Select Drugs policy

Policy:

A medication with alternative or alternatives is medically necessary when ALL of the following are met:

1. FDA approved, or compendia supported indication; and
2. Request is not for an excluded benefit (i.e., cosmetic); and
3. Inadequate response or inability to tolerate the alternative(s)

Authorization duration: 1 year

Target	Prerequisite(s)	Category
Vasotec®, Zestril®, Altace®, Accupril®, Lotrel®, Epaned®	3 generic angiotensin-converting enzyme (ACE) inhibitors (e.g., lisinopril, enalapril)	ACE-Inhibitors
Absorica [LD] ®	2 of the following: Amnesteem®, Claravis®, Myorisan®, Zenatane®	Acne agents
Daytrana®, amphetamine ER 1.25mg/ml suspension [Adzenys® ER], Adzenys XR-ODT®, Dyanavel XR®, Mydayis®, Cotempla®, Evekeo ODT, Zenzedi®, Xelstrym™, Vyvanse®, methylphenidate (Relexxii®) tab ER osmotic release	2 generic ADHD stimulants (e.g., methylphenidate, amphetamines, etc.)	ADHD
Concerta®, Dexedrine® spansule, Desoxyn®, Ritalin, Ritalin LA®, Focalin XR®, Adderall®, Adderall XR®, Kapvay®, Intuniv®, Strattera®	generic equivalent of requested brand	ADHD
Azstarys®	One generic ADHD stimulants (e.g., methylphenidate, amphetamines, etc.)	ADHD
Quillichew®, Quillivant®, Aptensio®, Jornay PM®, Adhansia XR®, Metadate CD®	Generic methylphenidate	ADHD
Qelbree™, Onyda™ XR	ONE of the following: generic atomoxetine, generic guanfacine ER, generic clonidine ER	ADHD

Alrex®, Alocril®, Zerviate™, Bepreve®	Two of the following generics: azelastine, cromolyn sodium, epinastine), olopatadine	Allergic conjunctivitis
Aricept®, Adlarity®	Generic donepezil tablets	Alzheimer's Disease
Atacand [HCT]®, Avapro [Avalide]®, Cozaar [Hyzaar]®, Diovan [HCT]®, Micardis [HCT]®, Exforge [HCT]®, Benicar [HCT]®, Azor®, Tribenzor®, Edarbi®, Edarbyclor®, Tekturna [HCT]®,	3 generic angiotensin receptor blockers or combinations (e.g., losartan, olmesartan, valsartan tablet, etc.)	Angiotensin II receptor antagonists
Patanase®	Both of the following: fluticasone and flunisolide	Antiallergic agents
Rythmol® SR	Generic propafenone	Antiarrhythmics
Mysoline®	Generic primidone	Anticonvulsants
Lamictal®	generic lamotrigine	anticonvulsants
Keppra ®, Elepsia™ XR, Spritam®	generic levetiracetam	anticonvulsants
Briviact®, Xcopri®	One of the following generics: lamotrigine IR, levetiracetam IR, levetiracetam ER, oxcarbazepine IR, topiramate IR OR continuation of therapy with the requested drug	anticonvulsants
Lyrica®	Generic pregabalin	anticonvulsants
Topamax® [sprinkle]	topiramate	Anticonvulsants
Trokendi XR®, topiramate ER [Qudexy XR®], Eprontia™	Generic topiramate	Anticonvulsants
Oxcarbazepine ER [Oxtellar XR®]	generic oxcarbazepine	Anticonvulsants
Aptiom®	Three generic anticonvulsants OR continuation of therapy with Aptiom®	Anticonvulsants
Tegretol®, Tegretol XR®, Carbatrol®	generic carbamazepine	Anticonvulsants
Neurontin®	Generic gabapentin	Anticonvulsants
Felbatol®	Generic felbamate	Anticonvulsants
Zonegran®, Zonisade® suspension	Generic zonisamide	Anticonvulsants
Trileptal®	Generic oxcarbazepine	Anticonvulsants
Motpoly XR	Three generic anticonvulsants OR continuation of therapy with Motpoly XR	Anticonvulsants

Wellbutrin SR®, Wellbutrin XL®, Prozac®, Lexapro®, Zoloft®, Effexor XR®, Aplenzin®, bupropion ER 450mg [Forfivo® XL], Pexeva®, Pristiq®, Celexa®, Citalopram capsule, Sertraline capsule, Paxil [CR]®, Venlafaxine besylate tab ER	3 generic antidepressants (e.g., citalopram tablet, venlafaxine, bupropion, sertraline tablet, etc.)	Antidepressants
Symbyax®	Generic equivalent of requested brand	Antidepressants
Fetzima®, Viibryd®, Auvelity™	3 generic antidepressants (e.g., citalopram tablet, venlafaxine, bupropion, sertraline tablet, etc.) OR	Antidepressants

	continuous therapy with requested agent for a minimum of 2 weeks	
Trintellix®	2 generic antidepressants (e.g., citalopram tablet, venlafaxine, bupropion, sertraline tablet, etc.) OR continuous therapy with requested agent for a minimum of 2 weeks	Antidepressants
Cymbalta®, Drizalma®	Duloxetine	Antidepressants
Duetact®	Generic pioglitazone-glimepiride	Anti-diabetic
Actos®	Generic pioglitazone	Anti-diabetics
Glucotrol®, Amaryl®	3 generic sulfonylureas (e.g., glipizide, glyburide, glimepiride)	Anti-diabetics
Metformin tab 625mg	ONE of the following: metformin IR 500mg, 850mg, metformin 1000mg	Anti-diabetics
Riomet®	Metformin oral solution	Anti-diabetics
Xultophy	Soliqua	Anti-diabetics
Symlin®	Insulin within 180 days	Anti-diabetics
Non-preferred diabetic testing supplies (test strips and meters)	Accu-Chek Guide®	Anti-diabetics
Nesina®, Oseni®, Kazano®, Onglyza®, Kombiglyze®, Sitagliptin [Zituvio], Sitagliptin/Metformin [Zituvimet, Zituvimet XR]	Two of the following: Januvia® or Janumet® AND Tradjenta® or Jentadueto®	Anti-diabetics

Metformin tab ER Osmotic	Generic Glucophage XR (Metformin ER) tablets	Anti-diabetics
Qtern®, Steglatro™, Steglujan™, Segluromet™, Invokana®, Invokamet® [XR], bexagliflozin [Brenzavvy™], dapagliflozin, dapagliflozin/metformin ER	Minimum of 3-months trial with ONE of the following: Jardiance, Synjardy [XR], Glyxambi or Trijardy XR AND minimum of 3-months trial with ONE of the following: Farxiga or Xigduo XR	Anti-diabetics
Mytesi®	HIV therapy and ONE of the following: loperamide or diphenoxylate/ atropine	Antidiarrheal

Compro®	Generic prochlorperazine suppository	Anti-emetics
Sancuso®	One of the following: generic granisetron, generic ondansetron, aprepitant	Anti-emetics
Alphagan® P, Azopt®, Combigan®, Cosopt®, Cosopt® PF, Iopidine®, Istalol®, Timoptic® Ocudose	Minimum of 30-day trial with the generic equivalent of the requested brand	Anti-glaucoma agents
Betoptic®-S	Two generic ophthalmic beta blockers (e.g., timolol, betaxolol, levobunolol)	Anti-glaucoma agents
Allopurinol 200mg tablets	Generic allopurinol 100mg tablet	Anti-gout
Colchicine capsules [Mitigare®], Colcrys®, Gloperba®	colchicine tablets	Anti-gout
Febuxostat, Zyloprim®	generic allopurinol	Anti-gout
Uloric®	Both allopurinol and generic febuxostat	Anti-gout
Clemastine fumarate syrup	Both of the following: 2 second-generation generic antihistamines (e.g., loratadine, desloratadine, etc..) and generic clemastine fumarate tablets	Antihistamine
Clarinex®, Clarinex-D®, Dexchlorpheniramine/Ryclora®	BOTH of the following generics (desloratadine, carbinoxamine/Ryvent®)	Antihistamines
Bystolic®	Generic nebivolol	Antihypertensives

Clonidine ER [Nexiclon™ XR]	Both of the following generics: clonidine tablets and clonidine patches	Antihypertensives
Bethkis®, Kitabis®, Tobi® Nebulizer solution	Generic tobramycin nebulizer solution	Anti-infective
Firvanq®	Generic vancomycin 25mg/ml or 50mg/ml oral solution	Anti-infective
Nuvessa™, Cleocin® ovules, Cleocin® cream	ONE of the following: generic metronidazole gel or generic clindamycin cream	Anti-infective
Likmez™	Generic metronidazole	Anti-infective
Solosec®	Both of the following: (1) generic metronidazole vaginal gel or generic clindamycin	Anti-infective

	vaginal gel AND (2) metronidazole tablets or tinidazole tablets	
Vandazole™	ONE of the following: generic metronidazole vaginal gel or generic clindamycin vaginal gel	Anti-infective
Noxafil	Generic posaconazole	Anti-infectives
Zyvox	generic linezolid	Anti-infectives
Brexafemme®, Diflucan®	Generic fluconazole	Anti-infectives
Monurol®	Generic Fosfomycin tromethamine	Anti-infectives
Arimidex®	Generic anastrazole	Antineoplastic
Eulexin®	Generic flutamide	Antineoplastic
Jylamvo®	Generic methotrexate tablets	Antineoplastics
Sensipar®	Generic cinacalcet	Antiparathyroid agent
Effient®, Plavix®	Generic equivalent of the requested brand	Antiplatelets
Abilify Mycite®, Fanapt®, Caplyta™, Secuado®, Lybalvi™, Opipza™, Cobenfy™	2 generic antipsychotic agents (e.g., aripiprazole, paliperidone, quetiapine, risperidone, etc.) OR continuation of therapy with requested medication	antipsychotics

Abilify®, Geodon®, Risperdal®, Saphris®, Seroquel® [XR], Invega®, Zyprexa® [Zydis]	2 generic antipsychotic agents (e.g., aripiprazole, paliperidone, quetiapine, risperidone, etc.)	antipsychotics
Latuda®	Generic lurasidone tablets	antipsychotics
Xerese® cream	Generic acyclovir cream	Antiviral
Valtrex®	generic valacyclovir	Antivirals
Ativan®, Valium®, Xanax®, Xanax® XR, Klonopin®, Loreev™ XR	3 generic benzodiazepines (e.g., lorazepam, diazepam, alprazolam, clonazepam, etc.)	Benzodiazepine
Inderal LA®, Tenormin®, Tenoretic®, Kapspargo™, Coreg [CR]®, InnoPran XL®, Inderal XL®	3 generic beta blockers (e.g., propranolol, atenolol, metoprolol, etc.)	Beta blockers
Questran®, Welchol™ tablet, Welchol™ packet, Colestid®	2 generic bile acid sequestrants (e.g., colestipol, cholestyramine, colesevelam)	Bile acid sequestrants

Binosto®, Actonel®, Boniva®	2 generic bone resorption inhibitors (e.g., risedronate, alendronate, ibandronate)	Bone resorption inhibitors
Evista®	Generic raloxifene	Bone resorption inhibitors
Moviprep®, Plenvu®, Osmoprep®	One of the following: Suprep or Clenpiq or Suflave	Bowel prep agents
Golytely®, Nulytely®	PEG-3350 oral solution	Bowel prep agents
Uroxatral®, Cardura® [XL], Flomax®, Rapaflo®	2 generic alpha blockers (e.g., alfuzosin, doxazosin, tamsulosin, prazosin, terazosin)	BPH
Jalyn®, Avodart™	Generic equivalent of the requested brand	BPH
Entadfi™[3]	One of the following generics (alfuzosin, doxazosin, tamsulosin, terazosin, silodosin) AND ONE of the following: 5-alpha-reductase inhibitor (i.e., finasteride 5mg, dutasteride) OR Phosphodiesterase type 5 inhibitor (i.e., tadalafil 2.5mg, 5mg)	BPH

Caduet®	Generic amlodipine-atorvastatin	Calcium channel blocker and HMG CoA reductase inhibitor combination
Cardizem CD®, Levamlodipine, Conjupri®, Norvasc®, Cardizem LA®, Cardizem®, Verelan®	3 generic calcium channel blockers (e.g., amlodipine, diltiazem, nifedipine, verapamil, etc.)	Calcium channel blockers
Inpefa™	Minimum 3 months trial of Jardiance® and minimum 3 months trial of Farxiga®	Cardiovascular agents
Penicillamine [Cuprimine®], Trientine/Clovique [Syprine®/Cuvrior™]	Depen®	Chelating agents
Niaspan®	Generic niacin	Cholesterol lowering agents
Lovaza®	Omega-3-acid ethyl esters	Cholesterol lowering agents
Zetia®	generic ezetimibe	Cholesterol lowering agents

Uceris®, Entocort EC®	Generic oral budesonide	Corticosteroid
Prednisolone [Millipred®], Alkindi®	One generic oral corticosteroid {e.g., hydrocortisone, methylprednisolone)	Corticosteroid
Prednisone Delayed Release (Rayos®)	Three generic immediate-release oral corticosteroids (e.g., hydrocortisone, dexamethasone, prednisone, methylprednisolone, prednisolone, etc.)	Corticosteroid
Livtencity™[1]	Minimum 2 weeks duration or inability to tolerate One of the following: ganciclovir IV, oral valganciclovir, foscarnet IV, or cidofovir IV	Cytomegalovirus (CMV)
Valcyte®	Generic valganciclovir	Cytomegalovirus (CMV)
Eucrisa®, Opzelura®	One of the following: one generic topical steroid (e.g., triamcinolone, clobetasol, halobetasol, etc.) or one generic topical calcineurin inhibitor	Dermatological agents

Elidel®	One generic topical steroid (e.g., triamcinolone, clobetasol, halobetasol, etc.) or generic tacrolimus	Dermatological agents
Vtama®	Minimum 30-day supply (14-day supply for topical corticosteroids) of THREE of the following: medium or higher potency topical corticosteroid, generic topical calcineurin inhibitor (e.g., tacrolimus ointment), Eucrisa (crisaborole), Opzelura (Ruxolitinib), Zoryve (roflumilast) 0.15% cream	Dermatological agents
Zoryve® cream 0.15%	ALL of the following: generic topical steroid (e.g., triamcinolone, clobetasol, halobetasol, etc.), generic tacrolimus ointment/ Pimecrolimus cream, Eucrisa (crisaborole) ointment.	Dermatological agents

Protopic®	generic tacrolimus	Dermatological agents
Plaquenil®, Sovuna™	Generic hydroxychloroquine tablet	Disease-modifying Antirheumatic Agents
Pradaxa Pak	One of the following: Eliquis, Xarelto, generic dabigatran capsules	DOAC
Varenicline (Tyrvaya™), Vevye®	Both of the following: Restasis Multidose and Xiidra	Dry eye disease
Cequa®	Generic cyclosporine emulsion	Dry eye disease
Cialis®, Viagra®, vardenafil [Levitra®], vardenafil, avanafil [Stendra®]	One of the following: sildenafil or tadalafil AND no concurrent use of nitrate	Erectile dysfunction agent
Crinone 8%	Endometrin®	Fertility
Gonal-F®, Gonal-RFF®, Menopur®	Follistim AQ®	Fertility
Trilipix™	Generic fenofibrate	Fibric acid derivatives
Ursodiol [Reltone™], Urso® [Forte]	Generic ursodiol capsule	Gallstone agents
Canasa®	Generic equivalent of requested brand	Gastrointestinal agent
Carafate®	Generic sucralfate tablet or suspension	Gastrointestinal agent

Colazal®	Generic balsalazide	Gastrointestinal agent
Lialda®	Generic mesalamine delayed release tablet	Gastrointestinal agent
Librax®	Generic equivalent of requested brand	Gastrointestinal agent
Asacol HD®, Delzicol®	Generic equivalent of requested brand	Gastrointestinal agent
Lotronex®	Generic alosetron	Gastrointestinal agent
Gimoti™[5]	Generic oral metoclopramide	Gastrointestinal agent
Pentasa 500mg capsule	Generic mesalamine ER 500mg capsule	Gastrointestinal agent
Rectiv®	Generic nitroglycerin ointment	Gastrointestinal agent
Syndros®	Generic dronabinol	Gastrointestinal agent
Glucagen®, Gvoke®2, Glucagon® (Lilly)	ONE of the following: Glucagon® (Fresenius), Baqsimi®, Zegalogue®	Glucagon agents

Pepcid	Two of the generics: famotidine, nizatidine, cimetidine, ranitidine	H2- Antagonists
Lescol® XL, Lipitor®, Crestor®, Livalo®, Vytorin® Zypitamag®, Ezallor®, Zocor®, Ezetimibe/rosuvastatin [Roszet®], ezetimibe/atorvastatin, Altoprev®	3 generic HMG CoA reductase inhibitors (e.g., simvastatin, atorvastatin, rosuvastatin, pravastatin, etc.)	HMG Co A reductase inhibitors
Minivelle®, Vivelle-Dot®, Alora®	Generic estradiol patch	Hormone Replacement Therapy
Angeliq® tablet	One generic estrogen-progestin combination (e.g., estradiol-norethindrone acetate, Jinteli, Minvey)	Hormone Replacement Therapy
Femring®, Vagifem®, Estrace cream®	Generic estradiol vaginal cream or vaginal tablet	Hormone replacement therapy
Intrarosa®	Imvexxy™	Hormone replacement therapy
Depo-Estradiol®	Generic estradiol injection in oil formulation	Hormone replacement therapy
Inspra®, Carospir®	Both of the following: generic spironolactone, eplerenone	Hypertension

Vecamyl®	2 generic antihypertensives in different classes	Hypertension
Viberzi®	One antidiarrheal medication (e.g., loperamide) AND one antispasmodic (e.g., dicyclomine, etc.)	IBS
Amitiza®	BOTH of the following: Lactulose solution or lubiprostone and Linzess® or Symproic®	IBS
Trulance ®, Zelnorm®, Ibsrela®	Both of the following: Linzess® and One of the following: lactulose solution or lubiprostone	IBS
Motegrity®	ALL of the following: Linzess®, generic lactulose solution, and generic prucalopride	IBS
Xepi™, Altabax®	mupirocin	Impetigo agents
Arava®	Generic leflunomide	Inflammatory conditions

Accrufer®	One of the following generics: ferrous sulfate, ferrous gluconate, ferrous fumarate	Iron preparations
lactulose packet [Kristalose® packet]	lactulose solution	Laxative
Singulair®	Generic montelukast	Leukotriene modifiers
Zileuton ER, Zyflo®	Both of the following generics: montelukast and zafirlukast	Leukotriene modifiers
Soaanz®	Two generic loop diuretics (e.g., torsemide, furosemide)	Loop diuretics
Extavia®, Rebif [Rebidose] ®, Mavenclad®, Ponvory®, Tascenso ODT™	2 of the following: Avonex®, Betaseron®, glatiramer (Copaxone® 40mg, Glatopa®), Plegridy®, Vumerity®, Bafiertam®, dimethyl fumarate, Kesimpta® OR continuation of therapy with the requested agent	MS
Aubagio®	Generic teriflunomide	MS
Copaxone® 20mg	Generic glatiramer	MS
Gilenya® 0.5mg	Generic fingolimod	MS

Tecfidera®	Dimethyl fumarate AND one of the following: Vumerity® or Bafiertam®	MS
Conzip®, Tramadol solution [Qdolo®]	2 generic tramadol products	Narcotic analgesic
Butalbital/APAP 25/325mg tablet [Allzital®], Butalbital/APAP 50/300mg tabs/caps	Butalbital/APAP 50/325mg tabs	Non-Narcotic Analgesic
Zebutal®, Esgic®	Butalbital/APAP/Caffeine 50/325mg/40mg tabs OR caps	Non-Narcotic Analgesic
Anaprox DS®, Naprosyn®, EC-Naprosyn®, Cambia pack®, Celebrex®, Arthrotec®, Daypro®, Mobic®, Diclofenac capsule [Zipsor®], Fenoprofen, Fenortho™, Nalfon®, Relafen [DS®], indomethacin [Tivorbex®, Indocin®], Meloxicam [Vivlodex®], diclofenac [Zorvolex®], Ketoprofen [Kiprofen] caps, Cataflam®, ketorolac tromethamine nasal spray [Sprix®], Elyxyb™, meloxicam suspension, Naprelan®, oxaprozin [Coxanto™], Dolobid®	3 generic prescription strength NSAIDS (e.g., ibuprofen, naproxen, diclofenac, celecoxib, meloxicam caps/tabs, etc.)	NSAIDs

Bromsite®, Ilevro®, Nevanac®, Prolensa®	TWO of the following: generic Ketorolac op sol 0.5%, Flurbiprofen op sol 0.03%, diclofenac op sol 0.1%	Ophthalmic NSAIDs
Zioptan®, Vyzulta™, Xelpros®, Travatan Z®, Iyuzeh™	ONE of the following generics: latanoprost, bimatoprost, travoprost AND Lumigan®	Ophthalmic prostaglandins
Pred Forte® ophthalmic suspension, clobetasol ophthalmic suspension	One generic ophthalmic steroid suspension (e.g., Prednisolone ophthalmic suspension, fluorometholone ophthalmic suspension, dexamethasone ophthalmic suspension)	Ophthalmic steroids
Seglentis®	3 generic alternatives indicated for acute pain (e.g., hydrocodone/acetaminophen, tramadol, acetaminophen, oxycodone/acetaminophen, etc.)	Opioid analgesic

Oxycodone [Roxybond®]	Two generic opioid analgesics or documentation of a history of or a potential for drug abuse for individual or a member of the individual's household	Opioid analgesics
Dilaudid®, MS Contin®, Roxicodone®, Oxaydo®, Percocet®, Xodol®, Methadose®, Ultracet®, Ultram®, Fioricet® with codeine, Fioricet®	Generic equivalent of requested brand	Opioid analgesics
Benzhydrocodone/Acetaminophen (Apadaz®)	Generic Hydrocodone/Acetaminophen and generic oxycodone/acetaminophen	Opioid analgesics
Prolate®, Oxycodone/Acetaminophen 2.5-300mg, 5-300mg, 7.5-300mg, 10-300mg, Nalocet 2.5-300mg, Oxycodone/Acetaminophen solution 5/325mg	Generic oxycodone/acetaminophen tablet	Opioid analgesics
Oxycontin®, Oxycodone ER, Hysingla®	Xtampza® ER	Opioid analgesics
Relistor®	BOTH of the following: Symproic® and One of the following: lactulose solution or lubiprostone	Opioid induced constipation
Lofexidine [Lucemyra®]	Generic clonidine	Opioid withdrawal

Carbamazepine suspension, gabapentin solution, pregabalin solution, oxcarbazepine suspension, nortriptyline solution, fluoxetine solution, metformin solution, amlodipine (Katerzia, Norliqva), enalapril solution, lisinopril (Qbrelis) solution, valsartan solution, vancomycin solution, nitrofurantoin suspension, valganciclovir solution, indomethacin suspension, naproxen suspension, methotrexate (Xatmep) solution, pyridostigmine solution, Thyquidity solution, simvastatin (Flolipid) suspension, atorvastatin calcium (Atorvaliq) suspension	Oral solid dosage formulation (tablet or capsule) of the drug requested OR one of the following: drug will be administered via nasogastric or gastronomy tube; or member is unable to swallow an intact capsule or tablet	Oral liquid dosage formulations that have a tablet or capsule formulation available[6]
Gelnique®, Oxytrol®, Ditropan XL®, Detrol®, Detrol LA®	2 generic alternatives (e.g., solifenacin, oxybutynin, tolterodine, etc.)	Overactive bladder agents

Toviaz®, Gemtesa®	Both of the following: Myrbetriq® AND 2 generic alternatives (e.g., solifenacin, oxybutynin tabs/tab ER/syrup, tolterodine, etc.)	Overactive bladder agents
Vesicare®, Vesicare LS®	Generic solifenacin	Overactive bladder agents
Pancreaze®, Pertzye®, Viokace®	Both of the following: Creon® and Zenpep®	Pancreatic enzymes
Mestinon®	Generic pyridostigmine	Parasympathomimetic
Dhivy	Carbidopa-levodopa IR and carbidopa-levodopa ODT	Parkinson's disease
Gocovri®	Generic amantadine	Parkinson's disease
Ongentys®	Generic entacapone	Parkinson's disease
Neupro®	Generic pramipexole and ropinirole	Parkinson's Disease, Restless leg syndrome
Xadago®	generic rasagiline and selegiline	Parkinson's disease
Rytary®, Crexont®	generic carbidopa/ levodopa	Parkinson's disease
Lanthanum [Fosrenol®]	Generic sevelamer	Phosphate removing agents
Phoslyra® solution	Generic calcium acetate	Phosphate binder agents
Xphozah®, Velphoro®	Minimum 30-day supply of two of the following: calcium carbonate, calcium acetate, lanthanum carbonate, sevelamer carbonate, sevelamer HCL, Auryxia	Phosphate removing agents
Durlaza®	aspirin	Platelet inhibitors
DDAVP	generic desmopressin acetate nasal spray	Posterior pituitary hormones
Sorilux® (calcipotriene foam 0.005%)	3 prescription strength, generic topical corticosteroids	Psoriasis agents
Zoryve™ cream 0.3%	ONE of the following: generic topical corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, coal tar, or combination topical therapy	Psoriasis agents

Airsupra™	Both of the following: one inhaled corticosteroid (ICS) with albuterol AND minimum 30-day supply of brand Symbicort	Pulmonary
Pulmicort® suspension	Generic budesonide inhalation suspension	Pulmonary
Xopenex® nebulizer solution	Generic levalbuterol nebulizer solution	Pulmonary
ProAir Digihaler®, Proventil® Ventolin®, Xopenex®	albuterol HFA	Pulmonary
Alvesco®, Asmanex®, Qvar®, Armonair®, Flovent Diskus/ HFA®, Fluticasone HFA, Fluticasone AER	Two of the following: Arnuity Ellipta® and Pulmicort Flexhaler®	Pulmonary
Dulera®, AirDuo®, Fluticasone/Salmeterol HFA, Advair® Diskus, Fluticasone/vilanterol inhaler, Breyna AER	TWO of the following: Breo Ellipta®, Symbicort® or Advair® HFA	Pulmonary
Bevespi Aerosphere®, Duaklir®	ONE of the following: Anoro Ellipta®, Stiolto Respimat®	Pulmonary
Tudorza® Lonhala Magnair®, Seebri®, Yupelri™, Incruse® Ellipta, tiotropium brom cap	Spiriva®	Pulmonary
Budesonide-formoterol fumarate dihydrate aerosol	Six-month trial of brand Symbicort® within the previous 365 days	Pulmonary
Anusol®-HC, Hemmorex®-HC, Proctocort® suppositories, Anucort-HC	Generic hydrocortisone acetate suppositories	Rectal preparations

Pokonza™	Generic Potassium chloride (tablets, solution, capsules, packets, crystals, etc.)	Replacement preparations
Finacea®, Zilxi®, Epsolay®	Soolantra®	Rosacea
Rhofade®	Mirvaso®	Rosacea
Noritate®	Soolantra® or Mirvaso®	Rosacea
Evoxac®	Generic cevimeline	Sjogren's Syndrome agent
Metaxalone [Skelaxin®], Soma®, Zanaflex®, Cyclobenzaprine ER [Amrix ER®], Lorzone®, Orphenadrine w aspirin & Caffeine [Norgesic®, Norgesic Forte®, Orphengesic tab forte®]	2 generic skeletal muscle relaxants (e.g., carisoprodol, tizanidine, cyclobenzaprine, chlorzoxazone 500mg, etc.)	Skeletal muscle relaxants

Baclofen solution [Ozobax™], Baclofen solution [Ozobax™ DS], Baclofen suspension [Fleqsuvy™], Lyvispah™	Generic baclofen tablets	Skeletal muscle relaxants
Zoryve™ foam	Minimum duration of a 4-weeks of two of the following: (1) Corticosteroids (e.g., betamethasone, clobetasol); (2) Antifungals (e.g., ciclopirox, ketoconazole); (3) calcineurin inhibitors (e.g., tacrolimus)	Skin and mucous membrane agents
Rozerem™	Generic ramelteon	Sleep agents
Restoril®, Halcion®, Doral®	2 generic benzodiazepines indicated for sleep (e.g., temazepam, triazolam, quazepam, estazolam, etc.)	Sleep agents
Ambien® 5mg [CR 6.25mg], Lunesta® 1mg, 2mg, Zolpidem 7.5mg capsules	2 generic sleep aids (e.g., zolpidem tablets, zolpidem ER tablets, eszopiclone, zaleplon, etc.)	Sleep agents
Doxepin [Silenor®], Belsomra®, Dayvigo™	Two of the following: eszopiclone, zaleplon, zolpidem	Sleep agents
Quviviq™	Belsomra® AND Two of the following: eszopiclone, zaleplon, zolpidem	Sleep agents
Nuvigil®, Provigil®	generic modafinil or armodafinil	Sleep agents
Ortikos®	Generic budesonide cap 3mg DR (Entocort EC®)	Systemic glucocorticoid

Acticlate®, Avidoxy, Doryx DR®, Doryx MPC®, Minocin®, Minolira™ [4], Solodyn®[4], Vibramycin®, doxycycline hyclate [Targadox®], Minocycline ER [Ximino®][4], Seysara™ [4]; doxycycline hyclate 80mg ER, Lymepak, Monodoxyne XL, Monodxyne NL, doxycycline monohydrate 75mg and 150mg capsule and tablet	2 generic alternatives (e.g., doxycycline, minocycline, tetracycline)	Tetracyclines
Tetracycline tablet	Generic tetracycline capsule	Tetracyclines
Levothyroxine [Tirosint®], Ermeza™	Generic levothyroxine	Thyroid replacement
Actiq®, fentanyl citrate (Fentora®)	Generic oral transmucosal fentanyl citrate	TIRF

Tazorac®, tazarotene [Fabior®]	Tazarotene	Topical acne agents
Differin®, Retin-A®, Retin-A micro®, Atralin®, Altreno™, Aklief®, Adapalene pad 0.1%, Arazlo®, Avita®	2 generic topical vitamin A derivative products	Topical acne agents
Amzeeq®, Cleocin T®, Evoclin foam®, Azelex® cream®, Clindagel®, Onexton™	2 generic, topical antibiotic or topical antibiotic combination products	Topical acne agents
Dapson (Aczone®) gel	3 of the following generics: adapalene cream/gel, adapalene/benzoyl peroxide, clindamycin gel/lotion/solution, clindamycin/tretinoin, erythromycin/benzoyl peroxide, tretinoin cream/gel	Topical acne agents
Acanya®, Benzamycin gel®, Benzamycinpak gel®, Clindamycin/benzoyl peroxide 1% / 5%, Veltin gel®, Ziana®, Twyneo®, Cabtreo™ gel	Epiduo® Forte	Topical acne agents
Winlevi®	One generic topical vitamin A derivative product AND one generic topical antibiotic/topical antibiotic combination product	Topical acne agents
Lidoderm® patches, Ztlido™, Tridacaine [II]	generic lidocaine patch	Topical anesthetics
Loprox®, Extina®, Oxistat®, Ecoza®, Xolegel®, luliconazole [Luzu®], mico-zn-petro [Vusion®], Ertaczo®, sulconazole [Exelderm®], oxiconazole	2 generic, prescription strength, topical antifungals (e.g., ketoconazole, ciclopirox, etc.)	Topical antifungal

Carac®	Fluorouracil 0.5% topical cream	Topical antineoplastics
Duobrii®	All of the following: (1) Generic tazarotene cream; and (2) one high potency topical corticosteroid (e.g., clobetasol, betamethasone, halobetasol, fluocinonide); and (3) one of the following: (a) Enstilar®; or (b) Wynzora®, or brand/generic Taclonex® (calcipotriene-betamethasone)	Topical steroid
Clobex®, Olux/ Olux E®, Ultravate®, Topicort®, Kenalog®, Luxiq®, clocortolone pivalate [Cloderm®], Desowen®, flurandrenolide [Cordran®, Nolix®], Derma-smoothe®, Synalar®, Locoid®, Locoid Lipocream®, Halog®, Verdeso®, Capex®, Pandel®, Sernivo®, Lexette®, Bryhali®; diflorasone diacetate [Apexicon E®], triamcinolone ointment 0.05% /Tritocin [Trianex®], Impeklo™, Pramosone®, hydrocortisone [Texacort™], Impoyz™, Ala Scalp®	3 prescription strength, generic topical steroids	Topical steroid
Anafranil™, Pamelor®	3 generic tricyclic antidepressants (e.g., nortriptyline, amitriptyline, imipramine, etc.)	Tricyclic antidepressants
Rayaldee®	generic calcitriol	Vitamin D analog
Brand prenatal vitamins	3 generic prenatal vitamins (various)	Vit

Title: Propranolol oral solution (Hemangeol™)

Applicable Drugs:

Brand Name	Generic Name
Hemangeol	Propranolol hydrochloride

Policy:

Propranolol oral solution (Hemangeol™) is approved when all of the following are met:

1. Diagnosis of proliferating infantile hemangioma; and
2. Member is less than 1 year of age.

Authorization Duration: through member's age of 12 months

P&T Approval Date: 2/2026

Field Name	Field Description
Prior Authorization Group Description	**Proprotein Convertase Subtilisin/kexin 9 (PCSK9) Monoclonal Antibodies (mAbs)**
Drugs	Repatha (evolocumab), Praluent (alirocumab), Leqvio (inclisiran), Lerochol (lerodalcibep-liga) Any newly marketed PCSK9 inhibitor
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be cardiologist or specialist in treatment of lipid disorders
Coverage Duration	If the criteria are met, the initial request will be approved for up to a 6 month duration, and the reauthorization request will be approved for up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	**Initial Authorization** **For All Requests:** • Request is appropriate for member (e.g. age) as indicated in package labeling or standard of care guidelines • One of the following: o Provider indicates member's LDL-C is above goal OR o Genetic test submitted with request (for diagnosis of familial hypercholesterolemia (FH) only) • Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies. • Patient has tried and failed ezetimibe at a maximal tolerated dose or a medical reason was provided why the member is not able to use this therapy. • If prescriber indicates member is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents. • Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet". **Reauthorization for all indications:**

Revision/Review Date 5/2026	• Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report and the member has had a reduction in LDL from baseline • The patient's claim history shows consistent therapy (i.e. monthly fills) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Proton Pump Inhibitors and Other Acid Reducers

Applicable Drugs:

Brand Name	**Generic Name**
Aciphex® [Sprinkles]	rabeprazole
Dexilant®	dexlansoprazole
Prevacid® [Solutab]	lansoprazole
Nexium® [Suspension]	esomeprazole magnesium
Prilosec® [Suspension]	omeprazole
Protonix® [Suspension]	pantoprazole
Zegerid® Suspension	omeprazole/sodium bicarbonate
Konvomep™ Suspension	omeprazole/sodium bicarbonate
Voquezna	vonoprazan

Policy:

INITIAL CRITERIA Brand proton pump inhibitor capsules and tablets (e.g., Aciphex® tablets, Protonix® tablets, Dexilant® capsules, Prilosec® capsules), dexlansoprazole, generic esomeprazole or omeprazole-sodium bicarbonate (Konvomep™), vonoprazan (Voquezna®) is medically necessary when BOTH of the following are met:

1. An FDA or compendia approved indication; and
2. Inadequate response to a two-week trial of maximally tolerated dose or inability to tolerate THREE of the following generic proton pump inhibitors:
    1. Omeprazole
    2. Lansoprazole
    3. Pantoprazole
    4. Rabeprazole

Initial authorization duration: H. Pylori 14 days; all other indications 2 years

REAUTHORIZATION CRITERIA Brand proton pump inhibitor capsules and tablets (e.g., Aciphex® tablets, Protonix® tablets, Dexilant® capsules, Prilosec® capsules), dexlansoprazole, generic esomeprazole or omeprazole-sodium bicarbonate (Konvomep™), vonoprazan (Voquezna®) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Documentation of continued need for treatment beyond 2 years

Reauthorization duration: 2 years

INITIAL CRITERIA Formulations other than capsules or tablets (e.g., lansoprazole [Prevacid® solu-tab], rabeprazole (Aciphex®) Sprinkles, Zegerid® packet, Prilosec® granules for suspension, pantoprazole [Protonix® packets] and esomeprazole [Nexium®] packets) require prior authorization for members aged 12 years and older and are medically necessary when there is documentation of BOTH of the following:

1. An FDA approved indication or clinically accepted use; and
2. One of the following:
    a. Drug will be administered via nasogastric or gastrostomy tube; or
    b. Member is unable to swallow an intact capsule or tablet

Initial authorization duration: H. Pylori 14 days; all other indications 2 years

REAUTHORIZATION CRITERIA Formulations other than capsules or tablets (e.g. lansoprazole [Prevacid® solutab], rabeprazole [Aciphex®] Sprinkles, Zegerid® packet, Prilosec® granules for suspension, pantoprazole [Protonix® packets] and esomeprazole [Nexium®] packets) require prior authorization for members age 12 years and older and are medically necessary when BOTH of the following criteria are met:

1. Documentation of positive clinical response to therapy; and
2. Documentation of continued need for treatment beyond 2 years

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Pulmonary Biologics for Respiratory and Eosinophilic Conditions**
Drugs	Nucala (mepolizumab), Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Tezspire (tezepelumab) or any newly marketed agents
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• When being used for relief of acute bronchospasm or status asthmaticus • When used in combination with another monoclonal antibody for the treatment of respiratory or eosinophilic conditions
Required Medical Information	See "other criteria"
Age Restrictions	Per Package Insert
Prescriber Restrictions	Prescriber must be an allergist, pulmonologist, immunologist, rheumatologist, gastroenterologist, dermatologist, or other provider who specializes in the treatment of asthma or eosinophilic conditions, or in consultation with one of these specialists
Coverage Duration	If the above conditions are met, the initial request will be approved with a 4 month duration. All subsequent requests will be approved with a 6 month duration.
Other Criteria	**Initial Authorization:** Asthma: • Confirmed diagnosis of one of the following: o Nucala, Fasenra, and Cinqair: Severe Eosinophilic Asthma o Dupixent: Moderate-to-Severe eosinophilic asthma o Tezspire: Severe Asthma • Documentation has been provided of blood eosinophil count within ONE of the following ranges: o Nucala and Dupixent: ≥ 150 cells/mcL (within 6 weeks of request) OR ≥ 300 cells/mcL (within the past 12 months) o Fasenra: ≥ 150 cells/mcL (within the past 12 months) o Cinqair: ≥ 400 cells/mcL (within the past 12 months) o Tezspire: No baseline blood eosinophil counts are required • The member has a documented baseline FEV_1 < 80% of predicted with evidence of reversibility by bronchodilator response. o Tezspire ONLY: If age is < 18 years, the member has a documented baseline FEV_1 < 90% of predicted with evidence of reversibility by bronchodilator response • Documentation has been provided indicating that that the member continues to experience significant symptoms while compliant on a maximally tolerated inhaled corticosteroid with long-acting beta2 agonist (ICS/LABA) AND long-acting muscarinic antagonist (LAMA) (or a documented medical reason must be provided why the member is unable to use these therapies) and ONE of the following: o Nucala: ≥ 2 exacerbations in the past 12 months o Fasenra: ≥ 1 exacerbation in the past 12 months o Cinqair: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids

	○ Dupixent: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids or hospitalization ○ Tezspire: ≥ 2 exacerbations requiring systemic corticosteroids OR ≥ 1 exacerbation in the past 12 months requiring hospitalization • The prescribed dose is within FDA approved dosing guidelines <u>Chronic Obstructive Pulmonary Disease (COPD) *(Dupixent & Nucala only)*</u>: • Confirmed diagnosis of COPD • Documentation has been provided of blood eosinophil count within one of the following ranges: ○ Dupixent: ≥300 cells/mcL (within the past 12 months) ○ Nucala: ≥150 cells/mcL (within 6 weeks of request) OR ≥300 cells/mcL (within the past 12 months) • The member has a documented post-bronchodilator FEV_1/FVC ratio < 0.7 and post-bronchodilator FEV_1 of 20% to 80% predicted • Documentation has been provided indicating that that the member continues to experience significant symptoms (i.e., chronic productive cough) while compliant on maintenance triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta2 agonist (LABA), and inhaled corticosteroid (ICS) (or a documented medical reason must be provided why the member is unable to use these therapies) and ONE of the following: ○ ≥ 2 exacerbations in the past 12 months, where systemic corticosteroids were required for at least one of them ○ ≥ 1 exacerbation in the past 12 months requiring hospitalization • The prescribed dose is within FDA approved dosing guidelines <u>Oral Corticosteroid Dependent Asthma: *(Dupixent only)*</u> • Confirmed diagnosis of oral corticosteroid (OCS) dependent asthma with at least 5 mg oral prednisone or equivalent per day for at least 4 weeks within the last 3 months • The patient has a documented baseline FEV_1 < 80% of predicted with evidence of reversibility by bronchodilator response. • Documentation has been provided indicating patient still is having significant symptoms with ≥ 1 exacerbations in the previous 12 months requiring additional medical treatment, (emergency room visits, hospital admissions) while compliant on a high-dose inhaled corticosteroid with a long-acting B_2 agonist (ICS/LABA) AND a long-acting muscarinic antagonist (LAMA). If the patient has not utilized these therapies, a documented medical reason must be provided why patient is unable to do so. • The prescribed dose is within FDA approved dosing guidelines <u>Eosinophilic Esophagitis (EoE) (*Dupixent only):*</u> • Confirmed diagnosis of EoE by endoscopic biopsy • Documentation of baseline esophageal intraepithelial eosinophil count and Dysphagia Symptom Questionnaire (DSQ) scores • Member has a history of at least 2 episodes of dysphagia (with intakes of solids) per week in the last 4 weeks • Documented trial and failure, intolerance, or contraindication to one proton pump inhibitor at a maximally tolerated dose for a minimum of 8 weeks • The prescribed dose is within FDA approved dosing guidelines

Prurigo Nodularis (PN) (*Dupixent only*):

- Confirmed diagnosis of PN lasting for at least three months prior to request
- Member has a Worst-itch Numeric Rating Scale (WI-NRS) score of 7 or higher indicating severe or very severe itching
- Member has at least 20 PN lesions in total
- Documented trial and failure, intolerance, or contraindication to at least two of the following for a minimum of two weeks:
    - One medium to super-high potency topical corticosteroid
    - One topical calcineurin inhibitor
    - UVB phototherapy or psoralen plus UVA phototherapy
- The prescribed dose is within FDA approved dosing guidelines

Chronic Spontaneous Urticaria (CSU) (*Dupixent only*):

- Confirmed diagnosis of CSU
- Documented history of urticaria for at least 6 weeks
- Member remains symptomatic despite a minimum two week trial of a formulary second generation H1 antihistamine at the maximum tolerated dose; or has a medical reason for not utilizing a second generation antihistamine
- The prescribed dose is within FDA approved dosing guidelines

Bullous Pemphigoid (Dupixent only):

- Confirmed diagnosis of bullous pemphigoid
- Member has a Bullous Pemphigoid Disease Area Index (BPDAI) activity score ≥24
- Member has a Peak Pruritus Numeric Rating Scale (NRS) score ≥4
- Documented trial and failure, intolerance, or contraindication to at least three of the following:
    - High potency topical corticosteroids
    - Oral corticosteroids
    - Doxycycline
    - Immunosuppressive therapies (ex. azathioprine, mycophenolate, methotrexate, etc.)
- The prescribed dose is within FDA approved dosing guidelines

Eosinophilic granulomatosis with polyangiitis (EGPA) (*Nucala & Fasenra only*):

- Confirmed diagnosis of EGPA and eosinophilic asthma lasting for ≥6 months
- Member has a history of relapsing disease defined as at least one EGPA relapse requiring additional corticosteroids or immunosuppressant or hospitalization within the past 2 years OR member has a history of refractory disease defined as failure to attain remission in the prior 6 months following induction treatment with standard therapy
- Member must be on a stable dose of oral corticosteroids for at least 4 weeks prior to request
- Member has a blood eosinophil count ≥1,000 cells/mcL OR > 10% of total leukocyte count
- Documented trial and failure, intolerance, or contraindication to cyclophosphamide, azathioprine, methotrexate, rituximab, OR mycophenolate mofetil

Revision/Review Date 2/2026	• If the request is for Nucala, member must also have a documented trial and failure, intolerance, or contraindication to Fasenra • The prescribed dose is within FDA approved dosing guidelines <u>Hypereosinophilic Syndrome (HES) (*Nucala only*):</u> • Confirmed diagnosis of FIP1 like 1-platelet derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative HES lasting for ≥6 months without an identifiable non-hematologic secondary cause • Member has a history of two or more HES flares (worsening of HES-related symptoms necessitating therapy escalation or ≥2 courses of rescue oral corticosteroids) within the past 12 months • Member has a blood eosinophil count ≥1,000 cells/mcL • Documented trial and failure, intolerance, or contraindication to oral corticosteroids AND at least one second-line agent (e.g. hydroxyurea, interferon, imatinib, methotrexate, cyclophosphamide, cyclosporine, azathioprine) (member must be on stable dose of at least one agent for at least 4 weeks prior to request) **<u>Re-Authorization:</u>** 1. Documentation submitted indicates the member has clinically benefited from the medication (e.g. Asthma & COPD: improved FEV_1, reduced exacerbations; HES: symptomatic improvement, reduced oral corticosteroid dose; EGPA: reduction in relapse frequency or severity, disease remission, symptomatic improvement, reduced oral corticosteroid dose; EoE: histological remission, improvement in DSQ scores; PN: improvement in WI-NRS score, symptomatic improvement; CSU: decrease in severe itching or urticaria activity; bullous pemphigoid: sustained remission, improvement in Peak Pruritus NRS score) 2. The prescribed dose is within FDA approved dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Pulmonary Hypertension (PH) Agents**
Drugs	**Endothelian Receptor Antagonists (ERA):** ambrisentan (Letairis), Opsumit (macitentan), bosentan (Tracleer) **ERA and Phosphodiesterase-5 (PDE-5) Inhibitor Combinations:** Opsynvi (macitentan and tadalafil) **PDE-5 Inhibitors:** tadalafil (Adcirca/Tadliq), sildenafil (Revatio/Liqrev) **Prostacyclin Receptor Agonists:** Uptravi (selexipag) **Prostaglandin Vasodilators:** epoprostenol (Flolan/Veletri), Orenitram/Tyvaso/Tyvaso DPI. (treprostinil), treprostinil sodium (Remodulin), Ventavis (Iloprost) **Soluble Guanylate Cyclase Stimulators:** Adempas (riociguat) **Transforming Growth Factor-beta (TGF-beta) Signaling Modulator:** Winrevair (sotatercept-csrk) **and any other newly marketed PAH treatment agents.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist
Coverage Duration	Orenitram, Tyvaso, Adempas, or Ventavis: 3 months for initial request Opsynvi: 4 months for initial request Uptravi: Request will be approved for the titration pack for 28 days until the highest tolerated dose (maintenance dose) is achieved. Once the member has achieved maintenance dosing, further refills can be approved for a 6 month duration. For all others, if all of the conditions are met, the initial request will be approved for a 6 month duration. All reauthorization requests will be approved for a 6 month duration
Other Criteria	**Initial Authorization:** • Member has a confirmed diagnosis that is indicated in the FDA approved package insert or has other medically-accepted use • For Uptravi, Orenitram, Tyvaso, Tyvaso DPI, Ventavis, Remodulin, Adempas, ONE of the following: o Documented trial and failure of one PDE-5 inhibitor (e.g., sildenafil, tadalafil) AND one Endothelin Receptor Antagonist (bosentan, ambrisentan, or Opsumit) o Diagnosis of WHO Group 1 FC III with evidence of rapid disease progression or FC IV (Uptravi, Orenitram, Tyvaso, Ventavis, Remodulin ONLY) o Diagnosis of persistent/recurrent chronic thromboembolic

Revision/Review Date: 05/2026	pulmonary hypertension (CTEPH) WHO Group 4 after surgical treatment, or inoperable CTEPH (Adempas ONLY) o Diagnosis of PH-ILD WHO Group 3 (Tyvaso ONLY) • If the request is for sildenafil oral suspension, Liqrev (sildenafil) oral suspension, Tracleer (bosentan) tablet for suspension, or Tadliq (tadalafil) oral suspension, documentation has been submitted as to why patient is unable to use the same ingredient in a tablet dosage form (e.g., difficulty swallowing) • If the request is for Opsumit the patient must have a documented trial and failure or intolerance to ambrisentan and bosentan, or provide a medical reason why these therapies are not appropriate. • If the request is for Opsynvi, BOTH of the following: o Patient has been stable for at least 6 months on combination therapy consisting of a PDE-5 inhibitor AND an ERA o Documentation is provided as to why patient is unable to take individual pills for combination therapy (e.g. adherence due to pill burden) • If the request is for Winrevair, ALL of the following: o Documented trial and failure of, or contraindication tocombination therapy including one PDE-5 inhibitor AND one ERA OR Opsynvi o Documentation of platelet count of $\geq$ 50,000/mm^3 • Documentation of the patient's current weight, dosing, and titration schedule is provided (if applicable) • The medication is prescribed at a dose that is within FDA approved guidelines **<u>Re-authorization:</u>** • Documentation has been submitted indicating the clinical benefit of therapy (e.g. improvement in functional class, improvement in 6-minute walk test, exercise capacity, or hemodynamics). • Documentation of the patient's current weight, dosing, and titration schedule is provided (if applicable) • The medication is prescribed at a dose that is within FDA approved guidelines. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Pyruvate Kinase Activators**
Drugs	Pyrukynd (mitapivat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Age ≥18 years
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	If the conditions are met, the request will be approved for a 6-month duration for initial requests and a 6-month duration for renewal requests. **If the conditions are not met: may approve up to 14 days of a Pyrukynd Taper Pack to allow for discontinuation tapering

Other Criteria	**Initial Authorization:**
	• The prescribed dose is within FDA approved dosing guidelines
	• Diagnosis of hemolytic anemia with pyruvate kinase deficiency (PKD)
	• Documentation of at least two variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least one is a missense variant
	• Documentation that the member is **not** homozygous for the R479H variant
	• Documentation that the member **does not have** two non-missense variants of the PKLR gene, without the presence of another missense variant in the PKLR gene
	• Documentation of ONE of the following:
	  o The member does not regularly require blood transfusions (defined as requiring less than or equal to 3 red blood cell (RBC) transfusions in the past 52 weeks **and** no transfusions in the past 3 months) AND hemoglobin (Hb) level ≤ 10 g/dL
	  o The member has required more than or equal to 6 RBC transfusions in the past 12 months
	  ▪ Documentation of the number of transfusions and the number of red blood cell (RBC) units transfused
	• Prescriber attests that the member does not have moderate or severe hepatic dysfunction and will monitor liver function monthly for the first 6 months of treatment

Revision/Review Date: 11/2025	• Prescriber attests that the member does not have a history of a prior bone marrow or stem cell transplant • The member is not concurrently using hematopoietic-stimulating agents (e.g. Procrit or Retacrit) • Prescriber attests the member is taking at least 0.8mg of folic acid daily **<u>Reauthorization:</u>** • The prescribed dose is within FDA approved dosing guidelines • For the first reauthorization, documentation of benefit: increase in Hb ≥1.5 g/dL over baseline OR a reduction in transfusions, defined as ≥33% reduction in the number of red blood cell (RBC) units transfused over baseline • For subsequent reauthorizations: documentation of benefit: stabilization in Hb levels OR a sustained reduction in transfusions • If the reauthorization criteria are not met, may authorize up to 14 days of a Pyrukynd Taper Pack to allow for tapering. To reduce the risk of acute hemolysis, abrupt discontinuation of Pyrukynd should be avoided. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Quantity Level Limits for Pharmaceuticals Covered under the Prescription Drug Benefit

Applicable Drugs:

Medication	**Maximum Quantity per day**	**Quantity limit per rolling 30 days, unless otherwise specified (tablets, capsules, mL)**	
ADHD Agents			
Atomoxetine HCL (Strattera®) 10mg, 18mg, 25mg, 40mg	2	60	
Atomoxetine HCL (Strattera®) 60mg, 80mg, 100mg	1	30	
Clonidine HCL (Kapvay®) 0.1mg	4	120	
Clonidine (Onyda XR™)	4	120	
Guanfacine HCL (Intuniv ER®) 1mg, 2mg, 3mg, 4mg tablet	1	30	
Viloxazine (Qelbree™) 100 mg	1	30	
Viloxazine (Qelbree™) 150 mg, 200 mg	2	60	
Antiemetics			
Aprepitant (Emend®) 80mg	NA	8	
Aprepitant (Emend®) 40mg	NA	2	
Aprepitant (Emend®) 125mg	NA	4	

Aprepitant (Emend®) trifold pack	NA	4 packs	
Antidepressant			
Fluoxetine (Prozac weekly®)	NA	4	
Zuranolone (Zurzuvae™) 20mg and 25mg	2	NA	14 days supply in 365 days
Zuranolone (Zurzuvae™) 30mg	1	NA	14 days supply in 365 days
Antipsychotics			
xanomeline & trospium chloride (Cobenfy™)	2	60	
Anti-Seizure Agents			
Diazepam (Valtoco®) nasal spray	NA	5 boxes (10 units)	
Diazepam (Libervant™) buccal film	NA	10	
Midazolam (Nayzilam®) nasal spray	NA	5 boxes (10 single dose spray units)	
Antivirals/Antiinfectives			
Acyclovir (Sitavig®)		2/30	
Baloxavir marboxil (Xofluza™) Therapy Packs 2 x 20mg (40mg dose) 2 x 40mg (80mg dose)	NA	2 tablets (1 box)/28 days	

Baloxavir marboxil (Xofluza™) therapy packs 1 x 40mg (40mg dose) 1 x 80mg (80mg dose)	NA	1 tablet/28 days	
Delafloxacin (Baxdela®) tablet 450mg	NA	28 tablets per 14 days	

Fidaxomicin (Dificid®) tablets	NA	20/10 days	
Fidaxomicin (Dificid®) suspension	NA	136 ml per 10 days	
Isavuconazonium (Cresemba®) capsule 186mg	NA	68	
Isavuconazonium (Cresemba®) capsule 74.5 mg	NA	170	
Ibrexafungerp (Brexafemme®)	NA	4/28 days	
Lefamulin (Xenleta™)	NA	10 tablets for 5 days	
Linezolid (Zyvox®) tablet 600mg	NA	56 tablets per 28 days	
Linezolid (Zyvox®) oral suspension 100mg/5ml	NA	1680 ml per 28 days	
Lotilaner (Xdemvy™) ophthalmic solution	NA	10ml per 42 days	
Mebendazole (Emverm®)	NA	6/21 days	
Minocycline ER (Solodyn®, Minolira™, Ximino®)	NA	84 days' supply per 180 days	

Nirmatrelvir 10 x 150mg /ritonavir 10 x 100mg pack (Paxlovid 150-100)	NA	20 tablets per course, 2 courses per year	
Nirmatrelvir 20 x 150mg /ritonavir 10 x 100mg pack (Paxlovid 300-100)	NA	30 tablets per course, 2 courses per year	

Nitazoxanide (Alinia®) tablet	NA	12 tablets per 6 days	
Nitazoxanide (Alinia®) suspension	NA	300ml per 6 days	
Omadacycline (Nuzyra®) tablet 150mg	2.15	30 tablets per 14 days	28 days per 180 days
Oseltamivir (Tamiflu®) 6mg/ml	NA	180mL (3 bottles) per Rx	
Oseltamivir (Tamiflu®) 30mg	NA	20 per Rx	
Oseltamivir (Tamiflu®) 45mg, 75mg	NA	10 per Rx	
Posaconazole (Noxafil®) 100mg tab	NA	93	
Posaconazole (Noxafil®) 40mg/1ml oral suspension	20 ml	NA	
Quinine sulfate (Qualaquin®)	NA	60 capsule per 10 days	
Rifamycin tablet delayed release 194 mg (Aemcolo™)	NA	12 tablets per 30 days	
Sarecycline (Seysara™)	NA	84 days' supply per 180 days	

Tedizolid phosphate (Sivextro®)	1	6 per 6 days	28 days per 180 days
Tenofovir 300mg (Viread®)	1	30	
Emtricitabine/tenofovir disoproxil fumarate (Truvada® 200mg/300mg)	1	30	
Penciclovir (Denavir®)	NA	5 grams	

Zanamivir (Relenza®)	NA	1 Diskhaler per Rx	
Rifaximin (Xifaxan® 200mg)	NA	9/ 90days	
Acyclovir cream (Zovirax®)	NA	5g	
Acyclovir ointment (Zovirax®)	NA	30g	
Doxycycline DR (Doryx DR®) 200mg	1	7 days' supply per 30 days	
Miltefosine (Impavido®)	NA	84 per 28 days	
Bowel Prep Kits			
Peg 3350-electrolyte (Nulytely, Golytely)	NA	2 kits/year (8000ml)	
Peg-prep kits	NA	2 kits/year	
Contraceptives			
Diaphragm	NA	1 per year	
Ethinyl estradiol/etonogestrel (Nuvaring®)	NA	1per 28 days	

Ethinyl estradiol/norelgestromine (Xulane patch®, Zafemy®)	NA	3	
Ethinyl estradiol/segesterone acetate (Annovera®)	NA	1 per 365 days	
Condoms	NA	15	
Levonorgestrel 1.5mg (My Way®, Next Choice®, One Dose®, Plan B one-step®)	NA	3	

Levonorgestrel-ethinyl estradiol TD patch weekly (Twirla®)	NA	3	
Medroxyprogesterone acetate (Depo-Provera®)	NA	1 per 90 days	
Ulipristal (Ella®)	NA	3	
Diabetic Supplies/Drugs			
Blood glucose monitor	NA	2 per year	
Diabetic test strips	NA	200	
Freestyle Libre® reader; Dexcom® receiver	NA	2 per year	
Dexcom® transmitters	NA	4 per year	
Guardian® transmitters, Minilink® transmitters, Eversense® transmitters	NA	2 per year	
Freestyle Libre® 14-day sensor, Freestyle Libre® 2 sensor, Freestyle Libre® kit 3 sensor	NA	2 per 28 days	

Freestyle Libre® 10-day sensor	NA	3 per 30 days	
Dexcom G4, G5, G6, G7 sensor	NA	4 per 28 days	
Eversense® sensor	NA	2 per year	
Eversense® E3 sensor/transmitters	NA	2 per year	
Guardian sensor, Enlite sensor	NA	5 per 30 days	

Insulin injecting device (e.g., Novopen®)	NA	2 per year	
Insulin syringes and pen needles	NA	200	
Lancets	NA	200	
Insulin products	2mL	60	
Erectile Dysfunction			
Alprostadil (Caverject®, IFE-PG20)	NA	8 per 30 days	
Alprostadil (Edex®, Muse®)	NA	8 per 30 days	
Avanafil (Stendra®)	NA	8 per 30 days	
Sildenafil (Viagra®)	NA	8 per 30 days	
Tadalafil (Cialis®) 2.5mg, 5mg	1	30	
Tadalafil (Cialis®) 10mg, 20mg	NA	8	
Vardenafil (Levitra®, Staxyn®)	NA	8	
GLP-1 (diabetic and obesity)			

Exenatide (Bydureon BCise)	0.15	4 syringes per 28 days	
Exenatide (Byetta®) 10 mcg/0.04ml	0.08	1 syringe	
Exenatide (Byetta®) 5 mcg/0.02ml	0.04	1 syringe	
Tirzepatide (Mounjaro™)	0.08	4 syringes per 28 days	
Semaglutide (Ozempic®) 2mg/1.5ml	0.06	1 syringe per 28 days	

Semaglutide (Ozempic®) 2mg/3ml, 4mg/3ml, 8mg/3ml	0.11	1 syringe per 28 days	
Semaglutide (Rybelsus®)	1	30	
Dulaglutide (Trulicity®)	0.08	4 syringes per 28 days	
Liraglutide (Victoza®)	0.3	3 syringes	
Liraglutide (Saxenda®)	0.5	5 syringes	
Semaglutide (Wegovy®) 0.25mg/0.5ml, 0.5mg/0.5ml, 1mg/0.5ml	0.08	4 syringes per 28 days	
Semaglutide (Wegovy®) 1.7mg/0.75ml, 2.4mg/0.75ml	0.11	4 syringes per 28 days	
Tirzepatide (Zepbound®)	0.08	4 per 28 days	
Injectable Fertility			
Follitropin Beta (Follistim AQ®) 75 unit vial	NA	60	

Follitropin Beta (Follistim AQ®) 150 unit vial	NA	30	
Follitropin Beta (Follistim AQ®) 300 unit cartridge	NA	15	
Follitropin Beta (Follistim AQ®) 600 unit cartridge	NA	8	
Follitropin Beta (Follistim AQ®) 900 unit cartridge	NA	5	

Follitropin Alfa (Gonal-F®) 450 units vial	NA	10	
Follitropin Alfa (Gonal-F®) 1050 units vial	NA	5	
Follitropin Alfa (Gonal-F RFF®) 300/0.5ml pen injector	NA	15	
Follitropin Alfa (Gonal-F RFF®) 450/0.75ml pen injector	NA	10	
Follitropin Alfa (Gonal-F RFF®) 900/1.5ml pen injector	NA	5	
Follitropin Alfa (Gonal-F RFF®) 75 unit vial	NA	60	
Menotropins (Menopur®)75 units vial	NA	180	
Migraine Agents			
Atogepant (Qulipta™)	1	30	

Eletriptan (Relpax®) 20mg, 40mg	NA	12	
Butorphanol nasal spray	NA	10	
Dihydroergotamine (Migranal®)	NA	8	
Dihydroergotamine mesylate HFA (Trudhesa™)	NA	12/28 days	
Emgality 100mg/ml	NA	9 injections/ 180 days	
Frovatriptan (Frova®) 2.5mg	NA	18	

Lasmiditan (Reyvow™) 50mg	NA	4	
Lasmiditan (Reyvow™) 100mg	NA	8	
Naratriptan 1mg, 2.5mg	NA	9	
Rimegepant (Nurtec ODT®)	NA	18	
Rizatriptan 5mg and 10mg	NA	12	
Sumatriptan (Imitrex®) 4mg injections	NA	14 kits (28 injections)	
Sumatriptan (Imitrex®) 6mg injections	NA	9 kits (18 injections)	
Sumatriptan (Imitrex®) 5mg/actuation nasal spray	NA	36	
Sumatriptan (Imitrex®) 20mg/actuation nasal spray	NA	18	

Sumatriptan (Imitrex®) 6mg/0.5ml subcutaneous cartridge/pen injection	NA	9ml	
Sumatriptan (Imitrex®) 4mg/0.5ml subcutaneous cartridge/pen injection	NA	14ml	
Sumatriptan (Imitrex®) 25mg, 50mg, 100mg	NA	18	
Sumatriptan (Onzetra Xsail®) nasal	NA	16	
Sumatriptan (Tosymra®)	NA	12 single dose nasal sprays	

Sumatriptan/Naproxen (Treximet®) 85mg/500mg	NA	18	
Sumatriptan (Zembrace symtouch®) 3mg/0.5mL	NA	8	
Ubrogepant (Ubrelvy™)	NA	16	
Zavegepant (Zavzpret™)	0.27	8	
Zolmitriptan (Zomig®, Zomig ZMT®) 2.5mg, 5mg	NA	9	
Zolmitriptan (Zomig®) 2.5mg, 5mg nasal spray	NA	9	
Miscellaneous			
Adalimumab 10mg/0.1ml	0.08	2 injections per 28 days	

Adalimumab 20mg/0.2ml	0.08	2 injections per 28 days	
Adalimumab 40mg/0.8ml, 40mg/0.4ml	0.08	2 injections per 28 days	
Adalimumab 80mg/0.8ml	0.08	2 injections per 28 days	
Alpelisib (Vijoice®) 250mg	2	60	
Alpelisib (Vijoice®) 50mg, 125mg	1	30	
Baclofen suspension (Fleqsuvy ®)	16 ml	480 ml	
Belumosudil (Rezurock™)	1	30	

Birch triterpenes (Filsuvez®)	NA	19 tubes per 30 days	
Bremelanotide (Vyleesi™)	NA	8	
Budesonide (Eohilia™)	20ml	600ml	
Budesonide (Tarpeyo™)	4	120	
Caplacizumab-yhdp (Cablivi®)	1 kit (11mg)	30 days' supply per 365 days	
Celecoxib (Elyxyb™)	4.8 ml	144 ml	
Cenegermin-BKBJ (Oxervate™)	2	60	
Cyclosporine (Restasis®, Cequa®)	2	60	
Cyclosporine (Verkazia®)	4	120	

Cyclosporine (Vevye®)	0.2	6	
Cysteamine (Cystaran®) 0.44% ophthalmic solution	NA	4 bottles/30 days	
Cysteamine (Cystadrops®)	NA	20/28 days	
Diclofenac (Flector®) patch	2	60	
Diclofenac (Licart®) patch	1	30	
Diclofenac potassium (Zipsor®)	4	120	
Doxepin 5% cream (Prudoxin®, Zonalon®)	NA	45g/ 90 days	
Epinephrine pens/auto-injectors (Epi-Pen®, Auvi-Q®, Symjepi™)	NA	3 twin packs (6 injections) per 180 days	

Eplontersen (Wainua™)	NA	0.8 ml per 28 days	
Fecal microbiota spores, live-brpk (Vowst™)	NA	24 capsules per 1 year (2 treatment courses)	
Sparsentan (Filspari™) 200mg, 400mg	1	30	
Gimoti®	NA	56 days' supply per 180 days	
Glycopyrrolate (Dartisla ODT™)	4	120	
Glycopyrronium (Qbrexza™)	1	30	

Icatibant (Firazyr®/Sajazir™) 30mg/3ml syringe	NA	27mL	
Ketorolac tromethamine (Sprix®)	NA	5	
Levacetylleucine (Aqneursa™)	4 packets	120 packets	
Levoketoconazole (Recorlev®)	8	240	
Lidocaine (Lidoderm®, Ztlido™, Tridacaine [II]) patch	3	90	
Lifitegrast (Xiidra®)	2	60	
Maribavir (Livtencity™)	4	224/56 days	
Mavacamten (Camzyos™)	1	30	
Mavorixafor (Xolremdi™)	4	120	
Mesalamine (Pentasa®) 250mg	4		

Migalastat (Galafold®)	NA	14 tablets per 28 days	
Nalmefene (Opvee®)	NA	6	
Naloxone (Zimhi®)	NA	3ml (6 units)	
Naloxone (Kloxxado™)	NA	6	
Naloxone (Rextovy™)	0.2	6	
Nedosiran (Rivfloza™) 80mg/0.5ml	NA	2 vials per 28 days	

Nedosiran (Rivfloza™) 128mg/0.8ml, 160mg/ml	NA	1 syringe per 28 days	
Oxandrolone 2.5mg	8	30 days/180 days	
Oxandrolone 10mg	2	30 days/180 days	
Osilodrostat (Isturisa®) 1mg	8	240	
Osilodrostat (Isturisa®) 5mg	2	60	
Osilodrostat (Isturisa®) 10mg	6	180	
Oteseconazole (Vivjoa™)	N/A	18 tablets per 180 days	
Perfluorohexyloctane (Miebo™)	0.4	12	
Pitolisant (Wakix®) 4.45mg	2	60	
Pitolisant (Wakix®) 17.8mg	2	NA	
Resmetirom (Rezdiffra™)	1	30	

Ruxolitinib (Opzelura™)	NA	240 grams/28 days	
Sacubitril/valsartan (Entresto®) tablets	2	60	
Sacubitril/valsartan (Entresto®) sprinkles	4	120	
Sodium oxybate (Lumryz™)	1 packet	NA	

Sodium oxybate (Xyrem®), calcium, magnesium, potassium and sodium oxybates (Xywav™)	18	540	
Lofexidine (Lucemyra™)	16	480	Two 14 days' supply in 365 days
Apomorpine (Kynmobi™)	5	NA	
Vericiguat (Verquvo®)	1	30	
Varenicline (Tyrvaya™)	NA	8.4ml (2 bottles)	
Voclosporin (Lupkynis™)	6	180	
Multiple sclerosis agents			
Dalfampridine (Ampyra®)	2	60	
Interferon beta-1a (Avonex®)	NA	4	
Interferon beta-1a (Rebif/Rebif Rebidose®)	NA	12	
Interferon beta-1b (Betaseron®)	NA	15	

Interferon beta-1b (Extavia®)	NA	15	
Glatiramer acetate (Copaxone® 20mg)	1	30	
Glatiramer acetate (Copaxone® 40mg)	NA	12	

Peginterferon beta-1a (Plegridy®)	NA	1mL per 28 days	
Oncology Agents			
Afatinib dimaleate (Gilotrif®) 20mg, 30mg, 40mg	1	30	
Asciminib (Scemblix®) 20 mg	2	60	
Asciminib (Scemblix®) 40mg	8	240	
Asciminib (Scemblix®) 100mg	4	120	
Avapritinib (Ayvakit™) 25mg, 50mg, 100mg, 200mg, 300mg	1	30	
Brigatinib (Alunbrig®) 90mg, 180mg and initiation pack	1	30	
Brigatinib (Alunbrig®) 30mg	4	120	
Enasidenib mesylate (Idhifa®) 50mg, 100mg	1	30	
Erlotinib (Tarceva®) 25mg	3	90	
Everolimus (Afinitor®, Torpenz®) tablet 2.5mg, 5mg, 7.5mg, 10mg	1	30	
Ibrutinib (Imbruvica®) 70mg capsule	1	30	
Ibrutinib (Imbruvica®) 140mg capsule	2	60	

Ibrutinib (Imbruvica®) 140mg, 280mg, 420mg tablet	1	30	
Momelotinib (Ojjaara) 100mg, 150mg, 200mg	1	30	
Niraparib tosylate (Zejula®) 100mg	1	30	
Niraparib/abiraterone (Akeega™) 50mg/500mg, 100mg/500mg	2	60	
Osimertinib mesylate (Tagrisso®) 40mg	1	30	
Pemigatinib (Pemazyre®) 4.5mg, 9mg, 13.5mg	1	30	
Pirtobrutinib (Jaypirca®) 50mg	1	30	
Ponatinib (Iclusig®) 10mg, 15mg	1	30	
Ruxolitinib (Jakafi®) 5mg, 10mg	2	60	
Talazoparib tosylate (Talzenna®) 0.25mg, 0.5mg	1	30	
Vandetanib (Caprelsa®) 100mg tablet	2	60	
Osteoporosis Agents			
Alendronate 70mg/75ml solution	NA	300mL per 28 days	
Alendronate (Fosamax® and Binosto®) 35mg, 70mg	NA	4 per 28 days	

Alendronate with Vitamin D (Fosamax plus D®) 70mg/2.8ml, 70mg/5.6ml	NA	4 per28 days	
Ibandronate (Boniva®) 150mg	NA	1	
Risedronate sodium (Actonel® and Atelvia®) 35mg	NA	4 per28 days	
Risedronate sodium (Actonel®) 150mg	NA	1 per30 days	
Proton Pump Inhibitor/Acid Reducer			
Dexlansoprazole (Dexilant®)	2	60	
Esomeprazole magnesium (Nexium®) and strontium capsules	2	60	
Esomeprazole magnesium (Nexium®) packet	1	30	
Lansoprazole (Prevacid®)	2	60	
Lansoprazole (Prevacid®) solu-tab	1	30	
Omeprazole (Prilosec®)	2	60	
Omeprazole/sodium bicarbonate (Konvomep®)	20ml	600ml	
Omeprazole/sodium bicarbonate (Zegerid®) packets	1	30	
Prilosec 2.5mg pak	1	30	
Pantoprazole sodium (Protonix®)	2	60	

Pantoprazole sodium (Protonix®) packet	1	30	
Rabeprazole (Aciphex®)	2	60	
Rabeprazole (Aciphex®) sprinkle	1	30	
Vonoprazan (Voquezna®) 10 mg tablets	1	30	
Vonoprazan (Voquezna®) 20 mg tablets	2	30	
Sedative Hypnotics			
Daridorexant (Quviviq™)	1	30	
Estazolam	1	30	
Eszopiclone (Lunesta®) 1mg	2	60	
Eszopiclone (Lunesta®) 2mg, 3mg	1	30	
Flurazepam HCL	1	30	
Lemborexant (Dayvigo™)	1	30	
Quazepam	1	30	
Ramelteon (Rozerem®)	1	30	
Suvorexant (Belsomra®)	1	30	
Tasimelteon (Hetlioz®)	1	30	
Temazepam (Restoril®)	1	30	
Triazolam (Halcion®)	1	30	

Zaleplon	1	30	
Zolpidem (Zolpimist®)	NA	7.7ml (1 pump)	
Zolpidem tartrate (Ambien®, Ambien CR®, Edluar®, Intermezzo®)	1	30	
Smoking Cessation Products			
Bupropion HCL	2	60	180 cumulative days' supply per 365 days
Nicotine gum/inhaler/lozenges	10	300	
Nicotine nasal spray (Nicotrol® NS)	NA	80ml per 30 days	
Nicotine patches	1	30	
Varenicline (Chantix®, Apo-varenicline)	2	60	
Bronchodilator Products			
Albuterol sulfate (Proair HFA, Proair Respiclick, Proair Digihaler, Ventolin HFA, Proventil HFA)	NA	2 inhalers per 30 days	
Levalbuterol tartrate (Xopenex HFA)	NA	2 inhalers per 30 days	
Ensifentrine (Ohtuvayre™)	2 vials or 5 ml	60 vials or 150 ml	

Policy:

General quantity limit criteria

Quantity limit requests are approved when ONE of the following is met: (drug specific criteria below).

1. Requests that exceed the cumulative daily dose, dose frequency, or duration of therapy approved or recommended by the FDA or as stated in accepted compendia1 are considered off-label and are reviewed per Off-Label Use policy, OR
2. Requests that do not exceed the cumulative daily dose, dose frequency or duration of therapy approved or recommended by the FDA or as stated in accepted compendia1: A quantity limit exceeding those listed in the following table is approved when ONE of the following is met:
    1. Documentation of the inability to reach the requested dose with higher strengths of commercially available dosage forms due to member specific characteristics (i.e., inability to swallow larger pills, malabsorption, presence of a feeding tube, etc.); or
    2. The requested dose is not commercially available; or
    3. The requested dose is used for titration or loading-dose purposes (one-time authorization)

1 Please refer to the Off-Label Use policy for definition of accepted compendia

Authorization duration: 2 years
Authorization duration for dose titration: 14 days

Drug specific quantity limit criteria:

Belumosudil (Rezurock™) specific criteria:

A quantity limit exceeding that listed is approved when BOTH of the following are met:

1. One of the following:
    a. Member is taking a strong CYP3A4 inducer; or
    b. Member is on a proton pump inhibitor; and
2. Quantity requested does not exceed 2 per day

Authorization duration: 2 years

Icatibant (Firazyr®, Sajazir®) specific criteria:

A quantity limit exceeding those listed is approved when BOTH of the following criteria are met:

1. The total dose does not exceed FDA approved maximum dose; and
2. ONE of the following:
    a. For Hereditary Angioedema (HAE)Types I and II: documentation of an inadequate response or inability to tolerate C1 inhibitor replacement therapy (e.g., Cinryze®, Berinert®); or
    b. For HAE non-Type I or II: documentation of medical necessity

Authorization duration: 2 years

Acute migraine Agents specific criteria:

An increased quantity of a migraine agent is approved when there is a diagnosis of acute treatment of migraine headache and all of the following inclusion criteria are met:

1. Trial of prophylactic treatment with one of the following: beta blocker, calcium channel blocker, tricyclic antidepressant, valproic acid, cyproheptadine calcitonin gene-related peptide receptor antagonist (CGRP) indicated for prophylaxis (e.g., Erenumab [Aimovig™], fremanezumab [Ajovy™] or galcanezumab [Emgality™] 120mg/ml) or topiramate; and
2. Requested quantity does not exceed the manufacturer-recommend maximum doses; and
3. The member has been examined by a neurologist within the past three years.

Authorization duration: 2 years

Proton pump inhibitor specific criteria:

Increased quantity limits of proton pump inhibitors are approved when ONE of the following is met:

1. Pathological hypersecretory condition including Zollinger-Ellison syndrome; or
2. Barrett's esophagus; or
3. Upper gastrointestinal bleed (gastric or duodenal); or

4. Inadequate response to once daily proton pump inhibitor therapy with ONE of the following:
    a. Gastroesophageal reflux disease (GERD) with nocturnal symptoms; or
    b. GERD or erosive esophagitis for member less than 11 years old; or
    c. Laryngopharyngeal reflux; or
    d. Treatment for the eradication of H pylori with triple therapy (duration of therapy will be limited to 14 days

Authorization duration: 2 years

Doxycycline DR (Doryx DR®) 200mg specific criteria

A quantity limit exceeding those listed is approved when ONE of the following are met:

1. Diagnosis of acne and inadequate response or inability to tolerate 2 generic alternatives (e.g doxycycline, minocycline, tetracycline); or
2. Other diagnosis approved by the FDA or as stated in accepted compendia are considered off-label and are reviewed per Off-Label policy

Authorization duration: 2 years

Smoking Cessation Agents specific criteria:

Additional days' supply of bupropion (Zyban®), Varenicline (Chantix®, Apo-varenicline) and Nicotine Replacements (Nicotine gum, patches, inhalers, and spray) are approved when all the following are met:

1. One month has passed since last treatment failure with any product indicated for smoking cessation; and
2. Member is enrolled in a Smoking Cessation Program (in person or online); and
3. Member is currently a smoker

Authorization duration: 6 months

Epinephrine pens/ auto-injectors

A quantity limit exceeding those listed may be considered with documentation that a member needs an additional supply based on medical necessity (where additional doses or storage at additional locations are required).

Authorization duration: 6 months

Lofexidine (Lucemyra®)

Criteria for approving more than two 14-day supplies:

Lofexidine (Lucemyra®): An exception for increased days' supply is approved when there is documentation that lofexidine (Lucemyra®) will be used concurrently with comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self-help programs, behavioral therapy, or other psychosocial services)

Authorization duration: 6 months

Caplacizumab-yhdp (Cablivi®)

Criteria for approving more than 30-day supply per 365 days:

Caplacizumab-yhdp (Cablivi®): Additional quantities will be approved when the total duration of therapy does not exceed 58 doses after the last plasma exchange.

Authorization duration: 30 days

Tedizolid phosphate (Sivextro®) specific criteria

Additional days' supply of Sivextro is approved when all of the following are met:

1. Prescribed by or in consultation with an infectious disease specialist; and
2. Submission of medical records (e.g., chart notes, susceptibility testing) supporting medical necessity for continuing treatment beyond 28 days

Authorization duration: 6 months

Omadacycline (Nuzyra®) specific criteria

Additional days' supply of Nuzyra is approved when all of the following are met:

1. Prescribed by or in consultation with an infectious disease specialist; and
2. Submission of medical records (e.g., chart notes, susceptibility testing) supporting medical necessity for continuing treatment beyond 28 days

Authorization duration: 6 months

Adalimumab specific criteria:

A quantity limit exceeding that listed is medically necessary when ONE of the following is met:

1. For 10mg/0.1ml request only, both of the following:
    1. Requested dose and frequency does not exceed maximum FDA recommendation per label; and
    2. Documentation of the inability to reach the target dose using 20mg/0.2ml or 40mg/0.8ml formulation; or
2. For 20mg/0.2ml request only, both of the following:
    1. Requested dose and frequency does not exceed maximum FDA recommendation per label; and
    2. Documentation of the inability to reach the target dose using 40mg/0.8ml formulation; or
3. For 40mg/0.8ml and 40mg/0.4ml request only, both of the following:
    1. Requested dose and frequency does not exceed maximum FDA recommendation per label; and
    2. The requested to achieve 80mg target dose for each injection; or
4. For 80mg/0.8ml request only, one of the following:
    1. Requested dose and frequency does not exceed maximum FDA recommendation per label; and
    2. The requested dose is used for loading dose purposes (one-time authorization); or

Authorization duration: 12 months

Authorization duration for loading dose: aligns with label

Black Box Warning as shown in the drug Prescribing Information:

Adalimumab products
SERIOUS INFECTIONS

- Patients treated with adalimumab products are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these

infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

- Discontinue drug if a patient develops a serious infection or sepsis.
- Reported infections include:
- Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before adalimumab products use and during therapy. Initiate treatment for latent TB prior to adalimumab product use.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
- Bacterial, viral and other infections due to opportunistic pathogens, including Legionella and Listeria.
- Carefully consider the risks and benefits of treatment with adalimumab products prior to initiating therapy in patients with chronic or recurrent infection.
- Monitor patients closely for the development of signs and symptoms of infection during and after treatment with adalimumab products, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

MALIGNANCY
Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including adalimumab products. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine or 6-mercaptopurine (6–MP) concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

Antivirals/Anti-infective
Truvada® (emtricitabine and tenofovir disoproxil fumarate), tenofovir, Viread® (tenofovir disoproxil fumarate)

Severe acute exacerbations of hepatitis B virus (HBV) have been reported in HBV-infected patients who have discontinued Truvada® and tenofovir. Hepatic function should be monitored closely in HBV-infected patients who discontinue Truvada® and tenofovir. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Truvada® (emtricitabine and tenofovir disoproxil fumarate)
TRUVADA used for HIV-1 PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initiating and at least every 3 months during use. Drug resistant HIV-1 variants have been identified with the use of TRUVADA for HIV-1 PrEP following undetected acute HIV-1 infection. Do not initiate TRUVADA for HIV-1 PrEP if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed.

Tenofovir

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals. A majority of these cases have been in women. Obesity and prolonged nucleoside exposure may be risk factors. Particular caution should be exercised when administering nucleoside analogs to any patient with known risk factors for liver disease; however, cases have also been reported in patients with no known risk factors. Treatment with VIREAD should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations).

Strattera®
Suicidal ideation in children and adolescents: increases the risk of suicidal ideation in short-term studies in children and adolescents with ADHD. Anyone considering the use in a child or adolescent must balance this risk with the clinical need. Co-morbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Patients who are started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Strattera® is approved for ADHD in pediatric and adult patients. Strattera® is not approved for major depressive disorder. Pooled analyses of short-term (6 to 18 weeks) placebo-controlled trials in children and adolescents (a total of 12 trials involving over 2200 patients, including 11 trials in ADHD and 1 trial in enuresis) have revealed a greater risk of suicidal ideation early during treatment in those receiving Strattera® compared to placebo. The average risk of suicidal ideation in patients receiving Strattera® was 0.4% (5/1357 patients), compared to none in placebo-treated patients (851 patients). No suicides occurred in these trials.

Impavido®
Impavido® may cause fetal harm. Fetal death and teratogenicity occurred in animals administered Impavido® at doses lower than the recommended human dose. Do not administer Impavido® to pregnant women. Obtain a serum or urine pregnancy test in females of reproductive potential prior to prescribing Impavido®.

Females of reproductive potential should be advised to use effective contraception during Impavido® therapy and for 5 months after therapy.

Fluoroquinolones (Baxdela®)
Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together including:

- Tendinitis and tendon rupture
- Peripheral neuropathy
- Central nervous system effects

Discontinue immediately and avoid the use of fluoroquinolones in patients who experience any of these serious adverse reactions.
Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid fluoroquinolones in patients with known history of myasthenia gravis.

Quinine sulfate (Qualaquin®)
QUALAQUIN use for the treatment or prevention of nocturnal leg cramps may result in serious and life-threatening hematologic reactions, including thrombocytopenia and hemolytic uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP). Chronic renal impairment associated with the development of TTP has been reported. The risk associated with QUALAQUIN use in the absence of evidence of its effectiveness in the treatment or prevention of nocturnal leg cramps outweighs any potential benefit.

Levoketoconazole (Recorlev®)
Cases of hepatotoxicity with fatal outcome or requiring liver transplantation have been reported with oral ketoconazole. Some patients had no obvious risk factors for liver disease. RECORLEV is associated with serious hepatotoxicity. Evaluate liver enzymes prior to and during treatment. RECORLEV is associated with dose-related QT interval prolongation. QT interval prolongation may result in life-threatening ventricular dysrhythmias such as torsades de pointes. Perform ECG prior to and during treatment.

Paxlovid (nirmatrelvir tablets; ritonavir tablets)
WARNING: SIGNIFICANT DRUG INTERACTIONS WITH PAXLOVID

PAXLOVID includes ritonavir, a strong CYP3A inhibitor, which may lead to greater exposure of certain concomitant medications, resulting in potentially severe, life-threatening, or fatal events.
Prior to prescribing PAXLOVID: 1) Review all medications taken by the patient to assess potential drug-drug interactions with a strong CYP3A inhibitor like PAXLOVID and 2) Determine if concomitant medications require a dose adjustment, interruption, and/or additional monitoring.
Consider the benefit of PAXLOVID treatment in reducing hospitalization and death, and whether the risk of potential drug-drug interactions for an individual patient can be appropriately managed.

Antidepressants
Prozac® Weekly™
Suicidal thoughts and behaviors: antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increased. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a reduction in risk with antidepressant use in patients aged 65 and older.
In patients of all ages who are started in antidepressant therapy, monitor closely for worsening and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.
Not approved for use in children less than 7 years of age.

Zurzuvae (zuranolone)
WARNING: IMPAIRED ABILITY TO DRIVE OR ENGAGE IN OTHER POTENTIALLY HAZARDOUS ACTIVITIES See full prescribing information for complete boxed warning. ZURZUVAE causes driving impairment due to central nervous system (CNS) depressant effects. Advise patients not to drive or engage in other potentially hazardous activities until at least 12 hours after administration. Patients may not be able to assess their own driving competence or the degree of impairment caused by ZURZUVAE

Attention Deficit Hyperactivity Disorder (ADHD)
Qelbree™
In clinical trials, higher rates of suicidal thoughts and behavior were reported in pediatric patients treated with Qelbree than in patients treated with placebo. Closely monitor for worsening and emergence of suicidal thoughts and behaviors.

Contraceptives

NuvaRing®, Xulane®, Annovera®, Twirla®

Cigarette smoking and serious cardiovascular events: cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive (CHC) use. This risk increases with age, particularly in women over 35 years of age and with the number of cigarettes smoked. For this reason, CHCs should not be used by women who are over 35 years of age and smoke.

Xulane®

Risk of venous thromboembolism: the risk of VTE among women aged 15-44 who used the patch compared to women who used several different oral contraceptives was assessed in five U.S. epidemiologic studies using electronic healthcare claims data. The relative risk estimates ranged from 1.2 to 2.2; one of the studies found a statistically significant increased relative risk of VTE for current users.

Pharmacokinetic profile of ethinyl estradiol: the PK profile for the patch is different from the PK profile for oral contraceptives in that it has a higher steady state concentration and a lower peak concentration. Area under the time-concentration curve (AUC) and average concentration at steady state (Css) for EE are approximately 60% higher in women than compared with women using an oral contraceptive containing 35 mcg of EE. In contrast, the peak concentration (Cmax) for EE is approximately 25% lower in women using the patch. It is not known whether there are changes in the risk of serious adverse events based on the differences in PK profiles of EE in women using norelgestromin and ethinyl estradiol transdermal system compared with women using oral contraceptives containing 30–35 mcg of EE. Increased estrogen exposure may increase the risk of adverse events, including VTE.

Depo-Provera®

Loss of bone mineral density: women may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible. It unknown if use during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life. It should not be used as a long-term birth control method (i.e., longer than 2 years) unless other birth control methods are considered inadequate.

GLP-1 (Diabetic and obesity)

Exenatide (Bydureon®/Bydureon BCise®), tirzepatide (Mounjaro™), semaglutide (Ozempic®), semaglutide (Rybelsus®), dulaglutide (Trulicity®), liraglutide (Victoza®), liraglutide (Saxenda®) , semaglutide (Wegovy®), tirzepatide (Zepbound)

RISK OF THYROID C-CELL TUMORS

Both Liraglutide and semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether these drugs causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced or semaglutide-induced rodent thyroid C-cell tumors has not been determined.
Liraglutide and semaglutide are contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of either liraglutide or semaglutide and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with liraglutide or semaglutide.

In rats, tirzepatide causes thyroid C-cell tumors. It is unknown whether tirzepatide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined
Tirzepatide is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors

Migraine Agents
Butorphanol tartrate NS

- Exposes patients and others to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing and monitor all patients regularly for the development of these behaviors and conditions.
- Serious, life-threatening, or fatal respiratory depression may occur with use. Monitor for respiratory for respiratory depression, especially during initiation or following a dose increase.
- Accidental exposure, especially by children, can result in fatal overdose.
- Prolonged use during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts.
- Interactions with drugs affecting cytochrome P450 isoenzymes: the concomitant use of butorphanol tartrate NS with all cytochrome P450 3A4 inhibitors may result in an increase in butorphanol plasma concentrations, which could increase or prolong adverse reactions and potentially fatal respiratory depression. Discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in butorphanol concentration. The effects of concomitant use or discontinuation of

cytochrome P450 3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors with tramadol or codeine are complex and requires careful consideration of the effects on the parent drug and the active metabolite.

- Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

Migranal®, Trudhesa™
Serious and/or life-threatening peripheral ischemia has been associated with the co-administration of dihydroergotamine with potent CYP 3A4 inhibitors including protease inhibitors and macrolide antibiotics. Because CYP 3A4 inhibition elevates the serum levels of dihydroergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of these medications is contraindicated.

Treximet® (sumatriptan/naproxen)
May cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
TREXIMET® is contraindicated in the setting of coronary artery bypass graft.
NSAID containing products cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events

Miscellaneous agents
Flector® patch, Zipsor®, Sprix®, Licart™, Elyxyb™

Cardiovascular thrombotic events: NSAIDs cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. It is contraindicated in the setting of coronary artery bypass graft surgery.
Gastrointestinal bleeding, ulceration, and perforation: NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

Entresto™
Fetal toxicity: when pregnancy is detected, discontinue as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

Oxandrin®

Peliosis hepatis, a condition in which liver and sometimes splenic tissue is replaced with blood-filled cysts, has been reported in patients receiving androgenic anabolic steroid therapy. These cysts are sometimes present with minimal hepatic dysfunction, but at other times they have been associated with liver failure. They are often not recognized until life-threatening liver failure or intra-abdominal hemorrhage develops. Withdrawal of drug usually results in complete disappearance of lesions. Liver cell tumors are also reported. Most often these tumors are benign and androgen-dependent, but fatal malignant tumors have been reported. Withdrawal of drug often results in regression or cessation of progression of the tumor. However, hepatic tumors associated with androgens or anabolic steroids are much more vascular than other hepatic tumors and may be silent until life-threatening intra-abdominal hemorrhage develops. Blood lipid changes that are known to be associated with increased risk of atherosclerosis are seen in patients treated with androgens or anabolic steroids. These changes include decreased high-density lipoproteins and sometimes increased low-density lipoproteins. The changes may be very marked and could have a serious impact on the risk of atherosclerosis and coronary artery disease.

Xyrem®, Xywav™

Central nervous system depression: Xyrem and Xywav are CNS depressants. Clinically significant respiratory depression and obtundation may occur in patients treated with Xyrem and Xywav at recommended doses. Many patients who received Xyrem and Xywav during clinical trials in narcolepsy were receiving central nervous system stimulants.

Misuse and abuse: Xyrem and Xywav are sodium salt of gamma hydroxybutyrate (GHB). Abuse of GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death. Because of because of the risks of CNS depression, abuse, and misuse, it is available only through a restricted distribution program called the Xyrem and Xywav REMS Program, using the central pharmacy that is specially certified. Prescribers must enroll in the program.

Verquvo® (vericiguat)

Embryo-fetal toxicity

Do not administer Verquvo® to a pregnant female because it may cause fetal harm.

Females of reproductive potential: Exclude pregnancy before the start of treatment. To prevent pregnancy, females of reproductive potential must use effective forms of contraception during treatment and for one month after stopping treatment.

Lupkynis™ (voclosporin)

Malignancies and serious infections
Increased risk for developing serious infections and malignancies with Lupkynis or other immunosuppressants that may lead to hospitalization or death.

Opzelura™ (ruxolitinib)
Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving Janus kinase inhibitors for inflammatory conditions. Higher rate of all-cause mortality, including sudden cardiovascular death have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. Lymphoma and other malignancies have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. Higher rate of MACE (including cardiovascular death, myocardial infarction, and stroke) has been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have occurred in patients treated with Janus kinase inhibitors for inflammatory conditions.

Sedative Hypnotics
Estazolam, Flurazepam HCL, quazepam, Restoril®, Halcion®, Nayzilam®, Valtoco®
Concomitant use of benzodiazepines and opioids: may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and duration to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

Nayzilam®, Valtoco®, Libervant
Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.
The unapproved use of benzodiazepines exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Before prescribing and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.
Although benzodiazepine is indicated only for intermittent use if used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of benzodiazepine may precipitate acute withdrawal reactions, which can be life-threatening. For patients using benzodiazepine more frequently than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue.

Zolpidem, Ambien ®, Ambien CR ®, Zolpimist®, Intermezzo®, Edluar®, (eszoplicone) Lunesta®, (zaleplon) Sonata®
Complex Sleep Behaviors: Complex sleep behaviors including sleepwalking, sleep driving, and engaging in other activities while not fully awake have been reported following use of the above

agents. Some of these events have resulted in serious injuries, including death. Discontinue use immediately if a patient experiences a complex sleep behavior.

Camzyos (mavacamten)
CAMZYOS can cause heart failure due to systolic dysfunction.
Echocardiogram assessments of left ventricular ejection fraction (LVEF) required before and during CAMZYOS use.
Initiation in patients with LVEF <55% not recommended. Interrupt if LVEF <50% or if worsening clinical status.
Certain CYP450 inhibitors and inducers are contraindicated in patients taking CAMZYOS because of an increased risk of heart failure.
CAMZYOS is available only through a restricted program called the CAMZYOS REMS Program.

Smoking Cessation Products
Bupropion hydrochloride (oral tablet/extended release tablet)
Suicidality and antidepressant drugs: although it is not indicated for the treatment of depression, it contains the same active ingredient as the antidepressant medication Wellbutrin®. Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term trials. These trials did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in subjects over age 24; there was a reduction in risk with antidepressant use in subjects aged 65 and older. In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.

Miscellaneous
Gimoti™
Tardive Dyskinesia: Metoclopramide can cause tardive dyskinesia (TD), a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage. Discontinue Gimoti in patients who develop signs or symptoms of TD. Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks because of the risk of developing TD with longer-term use.

Filspari™
HEPATOTOXICITY and EMBRYO-FETAL TOXICITY

- FILSPARI is only available through a restricted distribution program called the FILSPARI Risk Evaluation and Mitigation Strategies (REMS) because of these risks

- Some endothelin receptor antagonists have caused elevations of aminotransferases, hepatotoxicity, and liver failure
- Measure liver aminotransferases and total bilirubin prior to initiation of treatment and ALT and AST monthly for 12 months, then every 3 months during treatment
- Interrupt treatment and closely monitor patients developing aminotransferase elevations more than 3x Upper Limit of Normal (ULN)
- Based on animal data, FILSPARI can cause major birth defects if used during pregnancy
- Pregnancy testing is required before, during, and after treatment
- Patients who can become pregnant must use effective contraception prior to initiation of treatment, during treatment, and for one month after

Oncology Agents

Enasidenib mesylate (Idhifa)
WARNING: DIFFERENTIATION SYNDROME
Patients treated with IDHIFA have experienced symptoms of differentiation syndrome, which can be fatal if not treated. Symptoms may include fever, dyspnea, acute respiratory distress, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, lymphadenopathy, bone pain, and hepatic, renal, or multi-organ dysfunction. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

Ponatinib (Iclusig)

WARNING: ARTERIAL OCCLUSIVE EVENTS, VENOUS THROMBOEMBOLIC EVENTS, HEART FAILURE, AND HEPATOTOXICITY
Arterial occlusive events (AOEs), including fatalities, have occurred in ICLUSIG-treated patients. AOEs included fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease, and the need for urgent revascularization procedures. Patients with and without cardiovascular risk factors, including patients age 50 years or younger, experienced these events. Monitor for evidence of AOEs. Interrupt or discontinue ICLUSIG based on severity. Consider benefit-risk to guide a decision to restart ICLUSIG.
Venous thromboembolic events (VTEs) have occurred in ICLUSIG-treated patients. Monitor for evidence of VTEs. Interrupt or discontinue ICLUSIG based on severity.
Heart failure, including fatalities, occurred in ICLUSIG-treated patients. Monitor for heart failure and manage patients as clinically indicated. Interrupt or discontinue ICLUSIG for new or worsening heart failure.
Hepatotoxicity, liver failure and death have occurred in ICLUSIG-treated patients. Monitor liver

function tests. Interrupt or discontinue ICLUSIG based on severity.

Vandetanib (Caprelsa)

WARNING: QT PROLONGATION, TORSADES DE POINTES, AND SUDDEN DEATH
CAPRELSA can prolong the QT interval. Torsades de pointes and sudden death have occurred in patients receiving CAPRELSA. Do not use CAPRELSA in patients with hypocalcemia, hypokalemia, hypomagnesemia, or long QT syndrome. Correct hypocalcemia, hypokalemia and/or hypomagnesemia prior to CAPRELSA administration. Monitor electrolytes periodically. Avoid drugs known to prolong the QT interval. Only prescribers and pharmacies certified with the restricted distribution program are able to prescribe and dispense CAPRELSA

P&T Approval Date: Mar-20-2025

Prior Authorization Group Description	**Radicava**
Drugs	Pharmacy Benefit: Radicava ORS (edaravone) Medical Benefit: edaravone (Radicava)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If all of the criteria are met, initial requests will be approved for up to a 6 month duration and reauthorization requests will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date: 02/2026	**<u>Initial Authorization:</u>** • Member must have a diagnosis of ALS • Member must have a documented baseline evaluation of functionality using the revised ALS functional rating scale (ALSFRS-R) score ≥ 2 • Member's disease duration is 2 years or less • Member has a baseline forced vital capacity (FVC) of ≥ 80% • Member has been on riluzole (Rilutek), is beginning therapy as an adjunct to treatment with Radicava, or provider has provided a medical reason why member is unable to use riluzole • Dose is within FDA approved limits **<u>Reauthorization</u>** • Member has a documented positive response to therapy (e.g., improvement or stabilization of ALSFRS-R score) • Dose is within FDA-approved limits **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Resmetirom (Rezdiffra)

Applicable Drugs:

Brand Name	Generic Name
Rezdiffra	Resmetirom

Policy:

INITIAL CRITERIA: Resmetirom (Rezdiffra™) is medically necessary when ALL of the following are met:

1. Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH); and
2. Member does not have cirrhosis (e.g., decompensated cirrhosis); and
3. Member is 18 years of age or older; and
4. Submission of medical records (e.g., chart notes) confirming diagnosis has been confirmed by one of the following:
    1. FibroScan-aspartate aminotransferase (FAST); or
    2. MRI-aspartate aminotransferase (MAST); or
    3. Liver biopsy; and
5. Submission of medical records (e.g., chart notes) confirming disease is fibrosis stage F2 or F3 as confirmed by one of the following:
    1. FibroScan; or
    2. Fibrosis-4 index (FIB-4); or
    3. Magnetic Resonance Elastography (MRE); and
6. Presence of greater than or equal to 3 metabolic risk factors (e.g., Type 2 diabetes, hypertension, obesity); and
7. Submission of medical records (e.g., chart notes) confirming drug is used as adjunct to lifestyle modifications (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
8. Prescribed by or in consultation with one of the following:
    1. Gastroenterologist

2. Hepatologist

3. Endocrinologist

9. In patients without diabetes, or patients not taking another GLP1 receptor agonist: Documentation of trial and failure, or documented medical reason for not using Wegovy

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Resmetirom (Rezdiffra™) is medically necessary when ALL of the following are met:

1. Member demonstrates positive clinical response to therapy (e.g., NASH resolution, fibrosis stage improvement, etc.); and
2. Submission of medical records (e.g., chart notes) confirming drug will continue to be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
3. Member has not progressed to cirrhosis

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Prior Authorization Group Description	**Rhapsido**
Drugs	Rhapsido (remibrutinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist, immunologist, or dermatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For reauthorization, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 02/2026	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of chronic spontaneous urticaria for at least 6 weeks with uncontrolled symptoms • Member has had at least a 2-week trial and failure of, or has a contraindication to, at least two different H1 antihistamines (e.g. cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine) at four times the standard FDA-approved dose • Member has had at least a 2-month trial and failure of, or has a contraindication to, Xolair or Dupixent **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. change from baseline in weekly itch severity score, etc.) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Rifaximin (Xifaxan)

Applicable Drugs:

Brand Name	Generic Name
Xifaxan®	Rifaximin

Policy:

Hepatic disease with risk of hepatic encephalopathy

INITIAL CRITERIA: Rifaximin (Xifaxan®) 550 mg is approved when BOTH of the following are met:

1. Diagnosis of hepatic disease with risk for hepatic encephalopathy (i.e., previous episode of hepatic encephalopathy, advanced liver disease, hepatocellular carcinoma); and
2. Member is 18 years of age or older; and
3. Inadequate response or inability to tolerate lactulose

Initial authorization duration: 2 years (Maximum daily dose 2/day)

REAUTHORIZATION CRITERIA Rifaximin (Xifaxan®) 550mg is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years (Maximum daily dose 2/day)

Irritable Bowel Syndrome with Diarrhea

INITIAL CRITERIA: Rifaximin (Xifaxan®) 550mg is approved when All of the following are met:

1. Diagnosis of irritable bowel syndrome- diarrhea; and
2. Inadequate response or inability to tolerate an antispasmodic; and
3. Member is 18 years of age or older; and
4. Member does not exceed 3 courses (42 days) of therapy

Initial authorization duration: 3 months (max of 14 days/84 days; Maximum daily dose 3/day)

REAUTHORIZATION CRITERIA: Rifaximin (Xifaxan®) 550mg is re-approved when ALL of the following are met:

1. Diagnosis of irritable bowel syndrome – diarrhea; and
2. Symptoms of Irritable Bowel Syndrome continue to persist; and
3. Member demonstrates positive clinical response to therapy as evidenced by both of the following:
    a. Improvement in abdominal pain; and
    b. Reduction in the Bristol Stool Scale; and
4. Inadequate response or inability to tolerate an antispasmodic; and
5. BOTH of the following:
    a. Member does not exceed 3 courses (42 days) of therapy; and
    b. No documentation of rifaximin (Xifaxan®) treatment within the last 10 weeks.

Reauthorization duration: 3 months (max of 14 days/84 days; Maximum daily dose 3/day)

Traveler's Diarrhea Treatment

INITIAL CRITERIA: Rifaximin (Xifaxan®) 200 mg is approved when ALL of the following are met:

- Patient has the diagnosis of traveler's diarrhea
- Patient has tried and failed therapy with one formulary antibiotic or has a medical reason for not trying a formulary antibiotic (e.g., levofloxacin, azithromycin, sulfamethoxazole-trimethoprim)

Initial authorization duration: 1 month (max dose is 9 tablets/3 days)

P&T Approval Date: 11/2025

Title: Sacrosidase (Sucraid)

Applicable Drugs:

Brand Name	Generic Name
Sucraid®	Sacrosidase

Policy:

INITIAL CRITERIA: Sacrosidase (Sucraid®) is medically necessary when all of the following are met:

1. Diagnosis of sucrase deficiency (which is part of congenital sucrose-isomaltase deficiency [CSID]); and
2. Prescribed by or in consultation with gastroenterologist or geneticist

Initial Authorization duration: 3 months

REAUTHORIZATION CRITERIA: Sacrosidase (Sucraid®) is medically necessary when there is 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).

Reauthorization duration: 2 years

P&T Approval Date: 05/2026

Field Name	Field Description
Prior Authorization Group Description	**Safety Edit Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs and for previously approved non-formulary drugs outside of the scope of the statewide PDL: • Exceeding the Food and Drug Administration (FDA) or compendia max dose recommendations • Exceeding the FDA dosing or compendia administration frequency recommendations • Exceeding the FDA or compendia duration of therapy recommendations • Duplication of therapy error at Point of Service (POS) • Age Restriction error at POS • Day Supply Limit error at POS • Concurrent Use error at POS • Drug Drug Interaction error at POS
Criteria	**Exceeding the Food and Drug Administration (FDA) or compendia maximum dose, administration frequency or duration of therapy recommendations.** • The member must have a documented treatment failure with the drug at the maximum dose based on patient age/weight, administration frequency, or duration of therapy per FDA or compendia. AND • The provider must submit a medical reason why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history. **Duplication of therapy** <u>Transition from one agent to another</u> • If a provider has outlined a plan to transition a member to a similar drug or provided a dose titration schedule, the requested drug is approved for one month*. <u>Concurrent Therapy with two similar agents</u> • The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member's condition and treatment history. OR • The provider must submit disease state specific standard of care guidelines supporting concurrent therapy. **Age Restriction** • The provider must submit a medical reason why the drug is needed for a member whose age is outside of the plan's minimum or maximum age limit. AND • The indication and dose requested is supported by the Medical Compendia or current treatment guidelines.

Revision/Review Date: 2/2026	**Day Supply Limit** • An additional fill exceeding the day supply limit is needed based on a dose increase or is needed to achieve a total daily dose OR • The provider must submit a medical reason why an additional fill is needed outside of the plan's day supply limit. AND • The indication and dose requested is supported by the FDA, Medical Compendia or current treatment guidelines. **Concurrent Use/Drug-Drug Interaction** • The provider must submit a medical reason why treatment with both drugs is necessary for the member AND • The increased risk for side effects when taking the drugs together has been discussed with the member **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration	*One month approval for Duplication of therapy when transitioning from one agent to another and Day Supply Limit due to a dose increase. All Other Scenarios: 12 months

Title: Satralizumab-mwge (Enspryng®)

Applicable Drugs:

Brand Name	Generic Name
Enspryng™	Satralizumab-mwge

Policy:

INITAL CRITERIA: Satralizumab-mwge (Enspryng™) is approved when ALL of the following are met:

1. Diagnosis of neuromyelitis optica spectrum disorder (NMOSD); and
2. Member is anti-aquaporin-4 (AQP4) antibody positive; and
3. Prescribed by or in consultation with a neurologist or ophthalmologist; and
4. Member is 18 years of age or older

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Satralizumab-mwge (Enspryng™) is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

P&T Approval Date: 2/2026

Title: Seizure Disorder Agents

Applicable Drugs:

Brand Name	Generic Name
Epidiolex®	Cannabidiol
Diacomit®	Stiripentol
Onfi®, Sympazan®	Clobazam
Banzel®	Rufinamide
Fintepla®	Fenfluramine
Sabril®/Vigafyde	Vigabatrin

Policy:

Dravet Syndrome

INITIAL CRITERIA: Cannabidiol (Epidiolex) is approved when ALL of the following are met:

1. Member is 1 years of age or older; and
2. Baseline CBC, serum transaminases and total bilirubin obtained prior to initiating therapy; and
3. Diagnosis of Dravet syndrome; and
4. Inadequate response or inability to tolerate ONE of the following:
    1. Clobazam*; or
    2. Valproic acid; or
    3. Levetiracetam; o
    4. Topiramate; and
5. Documentation of concurrent use with additional anti-epileptic(s); and
6. Prescribed by or in consultation with a neurologist

INITIAL CRITERIA: Stiripentol (Diacomit®) is approved when ALL of the following are met:

1. Diagnosis of seizures associated with Dravet syndrome; and
2. Member is 6 months of age or older and weighing 7kg or more; and
3. Used in combination with clobazam*; and
4. Prescribed by or in consultation with a neurologist

INITIAL CRITERIA: Clobazam (Onfi®, Sympazan®) tablets, films, or oral suspension is approved when ALL of the following are met:

1. Member is 6 months of age or older and weighs greater than or equal to 7 kg; and
2. Diagnosis of seizures associated with Dravet Syndrome (DS); and
3. Used in combination with Diacomit (Stiripentol); and
4. Prescribed by or in consultation with a neurologist; and
5. For brand Onfi® and brand Sympazan® only, inadequate response or inability to tolerate generic clobazam tablets or oral suspension

INITIAL CRITERIA: Fenfluramine (Fintepla®) is approved when ALL of the following are met:

1. Diagnosis of Dravet Syndrome; and
2. Member is 2 years of age or older; and
3. Inadequate response or inability to tolerate ONE of the following:
    1. Clobazam*; or
    2. Valproic acid; or
    3. Divalproex sodium; or
    4. Topiramate; or
    5. Levetiracetam; and
4. Prescribed by or in consultation with a neurologist

Initial authorization duration: 2 years

CONTINUATION CRITERIA: Cannabidiol (Epidiolex®), Stiripentol (Diacomit®), clobazam (Onfi®, Sympazan®), or fenfluramine (Fintepla®) is re-approved when ALL of the following are met:

1. Documentation of reduction in seizure activity or intensity; and

2. Stiripentol (Diacomit®) only, used in combination with clobazam*; and
3. Prescribed by or in consultation with a neurologist

Continuation authorization duration: 2 years

Lennox-Gastaut Syndrome (LGS)
INITIAL CRITERIA: Cannabidiol (Epidiolex®) is approved when ALL of the following are met:

1. Member is 1 years of age or older; and
2. Baseline CBC, serum transaminases and total bilirubin obtained prior to initiating therapy; and
3. Diagnosis of Lennox-Gastaut syndrome (LGS); and
4. Inadequate response or inability to tolerate ONE of the following:
    1. Valproic acid; or
    2. Lamotrigine; or
    3. Topiramate; or
    4. Felbamate; or
    5. Rufinamide*; or
    6. Clobazam*; and
5. Documentation of concurrent use with additional anti-epileptic(s); and
6. Prescribed by or in consultation with a neurologist

INITIAL CRITERIA: Rufinamide (Banzel®) tablet or suspension is approved when ALL of the following are met:

1. Diagnosis of seizures associated with Lennox-Gastaut Syndrome (LGS); and
2. Used as adjunctive therapy; and
3. Member is 1 year of age or older; and
4. Inadequate response or inability to tolerate ONE of the following generics:
    1. Valproic acid; or
    2. Lamotrigine; or

3. Topiramate; or

4. Felbamate; or

5. Clobazam*; and

5. Prescribed by or in consultation with a neurologist; and

6. For rufinamide (Banzel®) suspension only; ONE of the following:

    1. Drug will be administered via nasogastric or gastronomy tube; or

    2. Member is unable to swallow an intact capsule or tablet

INITIAL CRITERIA: Fenfluramine (Fintepla®) is approved when ALL of the following are met:

1. Diagnosis of seizures associated with Lennox-Gastaut Syndrome (LGS); and

2. Member is 2 years of age or older; and

3. Inadequate response or inability to tolerate ONE of the following generics:

    1. Valproic acid; or

    2. Lamotrigine; or

    3. Topiramate; or

    4. Felbamate; or

    5. Clobazam; and

4. Prescribed by or in consultation with a neurologist

Initial authorization duration: 2 years

INITIAL CRITERIA: Clobazam (Onfi®, Sympazan®) tablets, films or oral suspension is approved when ALL of the following are met:

1. Member is 2 years of age and older; and

2. Diagnosis of seizure associated with Lennox-Gastaut Syndrome; and

3. Used as adjunctive therapy; and

4. Prescribed by or in consultation with a neurologist; and

5. For Brand Onfi® and brand Sympazan® only, inadequate response or inability to tolerate generic clobazam tablets or oral suspension

Initial authorization duration: 2 years

CONTINUATION CRITERIA: Cannabidiol (Epidiolex®), clobazam (Onfi®, Sympazan®), rufinamide (Banzel®), or fenfluramine (Fintepla®) is re-approved when there is documentation of reduction in seizure activity or intensity.

Continuation authorization duration: 2 years

Seizures associated with tuberous sclerosis complex
INITIAL CRITERIA: Cannabidiol (Epidiolex®) is approved when ALL of the following are met:

1. Member is 1 years of age or older; and
2. Baseline CBC, serum transaminases and total bilirubin obtained prior to initiating therapy; and
3. Diagnosis of seizures associated with tuberous sclerosis complex; and
4. Inadequate response or inability to tolerate ONE of the following:
    1. Vigabatrin*; or
    2. Carbamazepine; or
    3. Oxcarbazepine; and
5. Documentation of concurrent use with additional anti-epileptic(s); and
6. Prescribed by or in consultation with a neurologist

Initial authorization duration: 2 years

CONTINUATION CRITERIA: Cannabidiol (Epidiolex®) is re-approved when there is documentation of reduction in seizure activity or intensity.

Continuation authorization duration: 2 years

Refractory complex partial seizure or infantile spasms

INITIAL CRITERIA: Vigabatrin (Sabril®, Vigafyde™), is approved when ALL of the following are met:

1. One of the following:
    1. ALL of the following:
        1. Diagnosis of refractory complex partial seizures as adjunctive therapy; and

        2. Member is 2 years of age or older; and
        3. Used as adjunctive therapy; or
    2. BOTH of the following:
        1. Diagnosis of infantile spasms; and
        2. Member is 1 month to 2 years of age; and
2. For brand Sabril® only, inadequate response or inability to tolerate generic vigabatrin or vigadrone; and

3. Prescribed by or in consultation with a neurologist

Initial authorization duration: 2 years

CONTINUATION CRITERIA: Vigabatrin (Sabril®, Vigafyde™) is re-approved when there is documentation of reduction in seizure activity of intensity.

Continuation authorization duration: 2 years

P&T Approval Date: 2/2026

Title: Sickle Cell Disease Agents

Applicable Drugs:

Brand Name	Generic Name
Endari®	L-glutamine

Policy:

INITIAL CRITERIA L-glutamine (Endari®) is medically necessary when ALL of the following are met:

1. Diagnosis of sickle cell disease; and
2. Member is 5 years of age or older; and
3. Member has had 2 or more painful sickle cell crises within the past 12 months; and
4. Prescribed by or in consultation with a hematologist/oncologist or specialist with expertise in the diagnosis and management of sickle cell disease, and
5. Documentation of ONE of the following:
    a. Concurrent hydroxyurea therapy; or
    b. Inadequate response or inability to tolerate hydroxyurea

Initial authorization duration: 12 months

CONTINUATION CRITERIA L-glutamine (Endari®) is medically necessary when there is documentation of positive clinical response to therapy from baseline (e.g., reduction in the number of sickle cell crises, fewer hospitalizations due to sickle cell pain, etc.).

Continuation authorization duration: 2 years

P&T Approval Date: 11/2025

Title: Sinecatechins (Veregen®)

Applicable Drugs:

Brand Name	Generic Name
Veregen®	Sinecatechins

Policy:

Sinecatechins (Veregen®) is approved when all of the following are met:

1. Diagnosis of Condylomata acuminata (external genital and perianal warts); and
2. Member is immunocompetent; and
3. Member is 18 years of age or older; and
4. Inadequate response or inability to tolerate imiquimod (generic Aldara®)

Authorization duration: 4 months

Total duration of treatment is limited to 16 weeks per lifetime

P&T Approval Date: 2/2026

Title: Sirolimus topical gel (Hyftor™)

Applicable Drugs:

Brand Name	Generic Name
Hyftor™	sirolimus

Policy:

INITIAL CRITERIA: Sirolimus (Hyftor™) is approved when ALL of the following are met:

1. Diagnosis of facial angiofibroma associated with tuberous sclerosis complex; and
2. Member is 6 years of age or older; and
3. Member is not a candidate for laser therapy or surgical treatments; and
4. Prescribed by or in consultation with a dermatologist, neurologist, or geneticist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Sirolimus (Hyftor™) is re-approved with documentation of positive clinical response to therapy (e.g., improvement in size or redness of facial angiofibroma)

Reauthorization duration: 2 years

P&T Approval Date: 2/2026

Field Name	Field Description
Prior Authorization Group Description	Skyclarys (omaveloxolone)
Drugs	Skyclarys (omaveloxolone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA-approved prescribing information
Prescriber Restrictions	Prescriber must be a neurologist or in consultation with a neurologist or specialist with expertise in treating patients with Friedreich's Ataxia.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date 2/2026	**Initial Authorization:** • Diagnosis of Friedreich's Ataxia, confirmed via genetic testing (must submit documentation) • Modified FARS score ≥20 and ≤80 • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response to Skyclarys therapy (i.e. improvement in symptoms, slowing of disease progression, etc.) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Sleep Agents

Applicable Drugs:

Brand Name	Generic Name
Ambien® [CR]	zolpidem tartrate immediate and extended release (PA applies to generic 10mg IR and 12.5mg CR)
Edluar®	zolpidem sublingual tablets
Intermezzo®	zolpidem
Lunesta®	eszopiclone
Hetlioz®/Hetlioz LQ®	tasimelton

Policy:

Insomnia

INITIAL CRITERIA: Edluar® 5mg are approved when ALL of the following are met:

1. Diagnosis of insomnia; and
2. Member is 18 years of age or older; and
3. One of the following:
    1. Inadequate response or inability to tolerate TWO of the following:
        1. Eszopiclone
        2. Zaleplon
        3. Zolpidem; OR
    2. Inability to swallow capsules/tablets (i.e., dysphagia, gastrointestinal [GI] tubes)

INITIAL CRITERIA: Any of the following high dose products (brand and generic): zolpidem tartrate (Ambien®) 10mg, zolpidem tartrate ER (Ambien® CR) 12.5mg, eszopiclone (Lunesta®) 3mg or Edluar® 10mg is approved when ALL of the following are met:

1. Diagnosis of insomnia; and
2. Member is 18 years of age or older; and
3. Patient has been counseled on practices associated with good sleep hygiene (e.g., avoiding stimulants such as caffeine, nicotine, alcohol close to bedtime, etc.); and
4. Inadequate response to a two-week trial of the lower dose; and

5. For brand products with generic equivalents only, inadequate response or inability to tolerate a generic equivalent

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Edluar® 5mg, , zolpidem tartrate (Ambien®) 10mg, zolpidem tartrate ER (Ambien® CR) 12.5mg, eszopiclone (Lunesta®) 3mg, or Edluar® 10mg is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

Non-24 hour Sleep-Wake Disorder

INITIAL CRITERIA Tasimelteon (Hetlioz®) is approved when ALL of the following are met:

1. Prescribed by or in consultation with a sleep specialist or neurologist; and
2. 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); and
3. Member is 18 years of age or older; and

4. Member is totally blind (has no light perception); and
5. Member has circadian period greater than 24 hours; and

6. For brand Hetlioz only, inadequate response or inability to tolerate generic tasimelteon

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Hetlioz® is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

Smith-Magenis Syndrome

INITIAL CRITERIA Tasimelteon (Hetlioz®/Hetlioz LQ®) is approved when ALL of the following are met:

1. Prescribed by or in consultation with a sleep specialist or neurologist; and
2. Diagnosis of Smith-Magenis Syndrome; and
3. Member experiences nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking); and
4. One of the following:

    1. For Hetlioz only, member is 16 years of age or older; or

2. For Hetlioz LQ only, member is 3 to 15 years of age; and

5. For brand Hetlioz capsules only, inadequate response or inability to tolerate generic tasimelteon

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Hetlioz®/Hetlioz LQ® is re-approved when there is documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

Reauthorization duration: 2 years

P&T Approval Date: 2/2026

Title: Sodium oxybate (Xyrem®/Lumryz™)/calcium, magnesium, potassium and sodium oxybates (Xywav™)

Applicable Drugs:

Drug name	Generic name
Xyrem®	sodium oxybate solution
Xywav™	calcium, magnesium, potassium and sodium oxybates
Lumryz™	sodium oxybate extended-release oral suspension

Policy:

Cataplexy with narcolepsy (Type 1)

INITIAL CRITERIA: Sodium oxybate (Xyrem®) solution or calcium, magnesium, potassium and sodium oxybates (Xywav™) is approved when ALL of the following are met:

1. Diagnosis of Cataplexy with narcolepsy (Type 1); and
2. Member is 7 years of age or older; and
3. Diagnosis was confirmed by ONE of the following tests:
    1. Polysomnography (PSG); or
    2. Multiple sleep latency test (MSLT); and
4. Prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist; and
5. No concurrent use of sedative hypnotics and alcohol; and
6. Symptoms of cataplexy are present; and
7. Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present; and
8. For Xyrem® solution only, inadequate response or inability to tolerate sodium oxybate solution (by Hikma)

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Sodium oxybate (Xyrem®) solution or calcium, magnesium, potassium and sodium oxybates (Xywav™) is re-approved when ALL of the following are met:

1. Documentation to support the efficacy associated with the current regimen (including but not limited to reduction in the frequency of cataplexy attacks or an improvement in the Epworth sleepiness scale); and
2. There is no claim history of a sedative hypnotic agents within one year of the request; and
3. For Xyrem® solution only, inadequate response or inability to tolerate sodium oxybate solution (by Hikma); and
4. Yearly evaluation by a neurologist, psychiatrist, or sleep specialist

Reauthorization duration: 12 months

INITIAL CRITERIA: Sodium oxybate suspension extended-release (Lumryz™) is approved when ALL of the following are met:

1. Diagnosis of Excessive daytime sleepiness in narcolepsy (Type 2); and
2. Member is 7 years of age or older; and
3. Diagnosis was confirmed by ONE of the following tests:
    1. Polysomnography (PSG); or
    2. Multiple sleep latency test (MSLT); and

4. Inadequate response or inability to tolerate ALL of the following:
    1. Modafinil or armodafinil; and
    2. One of the following:
        1. One stimulant product (e.g., amphetamine, methylphenidate); or
        2. history of or potential for a substance use disorder; and
    3. Sunosi®; and
5. Prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist; and
6. Symptoms of cataplexy are absent; and
7. Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present; and
8. No concurrent use of sedative hypnotics and alcohol

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Sodium oxybate suspension extended-release (Lumryz™) is re-approved when ALL of the following are met:

1. Documentation to support the efficacy associated with the current regimen (including but not limited to reduction in the frequency of cataplexy attacks or an improvement in the Epworth sleepiness scale); and
2. There is no claim history of a sedative hypnotic agents within one year of the request; and
3. Yearly evaluation by a neurologist, psychiatrist, or sleep specialist

Reauthorization duration: 12 months

Idiopathic Hypersomnia (IH)

INITIAL CRITERIA: Calcium, magnesium, potassium and sodium oxybates (Xywav™) is approved when ALL of the following are met:

1. Diagnosis of idiopathic hypersomnia; and
2. Member is 18 years of age or older; and

3. Diagnosis was confirmed by ONE of the following tests:
    1. Polysomnography (PSG); or
    2. Multiple sleep latency test (MSLT); and
4. Symptoms of excessive daytime sleepiness (e.g., nap duration of longer than 60 minutes) are present; and
5. Prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist; and
6. No concurrent use of sedative hypnotics and alcohol

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Calcium, magnesium, potassium and sodium oxybates (Xywav™) is re-approved when ALL of the following are met:

1. Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy; and
2. There is no claim history of a sedative hypnotic agents within one year of the request; and
3. Yearly evaluation by a neurologist, psychiatrist, or sleep specialist

Reauthorization duration: 12 months

P&T Approval Date: 2/2026

Field Name	Field Description
Prior Authorization Group Description	Sohonos
Drugs	Sohonos (palovarotene)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Pregnancy • Use in patients younger than 8 years of age for females and 10 years of age for males
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an orthopedic specialist or provider who specializes in rare connective tissue diseases
Coverage Duration	If all of the criteria are met, the initial or reauthorization request will be approved for up to 12 months
Other Criteria	**Initial Authorization:** • Documented diagnosis of fibrodysplasia ossificans progressiva (FOP) • Documented genetic testing of ACVR1 R206H mutation • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of clinical benefit (i.e. volume reduction of heterotopic ossification) or worsening (i.e. flare-up presence and/or worsening of flare-ups) • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose
Revision/Review Date: 2/2026	**Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**SMN2 Splicing Modifiers for the Treatment of Spinal Muscular Atrophy (SMA)**
Drugs	Formulary: Evrysdi (risdiplam) Non-Formulary: Spinraza (nusinersen) Any other marketed agent within the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	Concomitant use of Evrysdi and Spinraza
Required Medical Information	For Evrysdi: Member's body weight
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a neurologist
Coverage Duration	For Evrysdi: If all of the criteria are met, the request will be approved for 6 months for initial authorization, followed by 12 months for reauthorization requests. For Spinraza: If all of the criteria are met, the request will be approved for 6 months for 5 doses (4 loading doses and 1st maintenance dose) for initial authorization, and 12 months for 3 additional maintenance doses for reauthorization requests.
Other Criteria	**Initial authorization** • Member has a confirmed diagnosis of SMA types I, II or III and the molecular genetic test with mutation analysis was submitted that is positive for the genetic deletion of the exon 7 of the survival motor neuron (SMN1) • For Spinraza: Documentation of genetic testing confirming either two or three copies of the SMN2 gene **OR** four copies of the SMN2 gene with symptomology of SMA • For Evrysdi: Documentation of genetic testing confirming two to four copies of the SMN2 gene • Baseline motor function or motor milestone achievement was Submitted with request [e.g., CHOP Infant Test of Neuromuscular Disorders (CHOP-INTEND) or Hammersmith Infant Neurological Examination (HINE) for Type 1 or Hammersmith Functional Motor Scale Expanded Scores (HFMSE) for Type II and Type III, or 6 minute walk test in subjects able to walk, Revised Upper Limb Module (RULM), or Motor Function Measure 32 (MFM-32)] • The request is for an FDA approved dose • Member has not previously received treatment with Zolgensma or Itvisma • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary medications appropriate for the requested use (per the references outlined in "Covered Uses" or has a medical reason why

Revision/Review Date 02/2026	these drug(s) cannot be used (e.g., intolerance, contraindication). For medications where there is only one formulary agent, only that agent must have been ineffective or not tolerated. **<u>Reauthorization</u>** • Documentation of clinical response was submitted with request (e.g., improvement or stabilization in motor function/motor milestone achievement scores using CHOP-INTEND or HFMSE, 6 minute walk test or HINE improvement in more categories of motor milestones than worsening, RULM, MFM-32, patient remains permanent ventilation free if no prior ventilator support) • The request is for an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Stimulants

Applicable Drugs:

Brand Name	**Generic Name**
Adderall® [IR/XR]	Amphetamine/Dextroamphetamine
Mydayis®	Amphetamine/Dextroamphetamine
Adzenys® [XR ODT/ER]	Amphetamine
Dyanavel® XR	Amphetamine
Evekeo® [ODT]	Amphetamine
Dexedrine® [IR/SA]	Dextroamphetamine sulfate
ProCentra®	Dextroamphetamine sulfate
Zenzedi®	Dextroamphetamine
Xelstrym®	Dextroamphetamine
Focalin® [IR/XR]	Dexmethylphenidate HCL
Vvyanse®	Lisdexamfetamine dimesylate
Aptensio® XR	Methylphenidate HCL
Concerta®	Methylphenidate HCL
Daytrana®	Methylphenidate HCL
Jornay PM™	Methylphenidate HCL
Metadate® [ER/CD]	Methylphenidate HCL

Methylin®	Methylphenidate HCL
Ritalin® [IR/LA]	Methylphenidate HCL
Quillichew® ER	Methylphenidate HCL
Quillivant® XR	Methylphenidate HCL
Cotempla®	Methylphenidate ER
Relexxii®	Methylphenidate ER
Azstarys™	Serdexmethylphenidate/Dexmethylphenidate

Policy:

Doses above the high cumulative dose are medically necessary when ALL of the following are met:

1. Inadequate response or inability to tolerate an alternative active ingredient within the CNS stimulant drug class prior to increasing the dose beyond the cumulative high dose limit; and
2. Member has been assessed for, and counseled by prescriber on ALL of the following:
    1. The risk for substance abuse; and
    2. The risk for cardiac related adverse events (i.e., hypertension); and
    3. The risk for new or worsening psychosis (i.e., maniac behavior); and
3. Requests that exceed the cumulative daily dose for the total daily dose of the drug, dose frequency, or duration of therapy approved or recommended by the FDA or as stated in accepted compendia are considered off-label and are reviewed per Off-Label Use policy

Authorization duration: 12 months

INITIAL CRITERIA: Amphetamine (Evekeo®) is medically necessary when ONE of the following is met:

1. Diagnosis of narcolepsy and ALL of the following:
    1. Prescribed by or in consultation with a neurologist or sleep specialist; and

2. Inadequate response or inability to tolerate generic modafinil or armodafinil; and

3. Diagnosis confirmed by ONE of the following tests:

    1. Polysomnography (PSG); or

    2. Multiple sleep latency test (MSLT); or

2. Attention Deficit Disorder with Hyperactivity (ADHD) and all of the following:

    1. Member is 3 to 17 years of age; and

    2. Inadequate response or inability to tolerate TWO of the following generic stimulant agents for ADHD:

        1. Methylphenidate
        2. Mixed amphetamine salts
        3. Dextroamphetamine
        4. Methamphetamine hydrochloride
        5. Dexmethylphenidate; or

3. Exogenous Obesity:

    1. If member has weight loss rider please refer to Weight Loss Agents policy for approval criteria and duration; or

    2. If member does not have a weight loss agents rider; deny as benefit exclusion*

*Drugs that are used for weight loss are covered only with weight loss rider.

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Amphetamine (Evekeo®) is re-approved when there is documentation of positive clinical response.

Reauthorization duration: 2 years

Quantity limit requests are approved when ONE of the following is met: (drug specific criteria below).

1. Requests that exceed the cumulative daily dose, dose frequency, or duration of therapy approved or recommended by the FDA or as stated in accepted compendia[1] are considered off-label and are reviewed per Off-Label Use policy, or

2. Requests that do not exceed the cumulative daily dose, dose frequency or duration of therapy approved or recommended by the FDA or as stated in accepted compendia[1]: A quantity limit exceeding those listed in the following table is approved when ONE of the following is met:

1. Documentation of the inability to reach the requested dose with higher strengths of commercially available dosage forms due to member specific characteristics (i.e., inability to swallow larger pills, malabsorption, presence of a feeding tube, etc.); or
2. The requested dose is not commercially available; or
3. The requested dose is used for titration or loading-dose purposes (one-time authorization)

[1] Please refer to the Off-Label Use policy for definition of accepted compendia

Authorization duration: 2 years
Authorization duration for dose titration: 14 days

Medication	**Maximum Quantity per day**	**Quantity limit per rolling 30 days, unless otherwise specified (tablets, capsules, mL)**
Amphetamine (Adzenys XR®)	1	30
Amphetamine (Adzenys ER®) 1.25mg/ml susp	15 ml	450
Dextroamphetamine/Amphetamine (Adderall®) 5mg, 7.5mg, 10mg, 12.5mg, 15mg and 20mg	3	90
Dextroamphetamine/Amphetamine (Adderall®) 30mg	2	60
Amphetamine/Dextroamphetamine ER (Mydayis™)	1	30
Dextroamphetamine/Amphetamine (Adderall XR®) 5mg, 10mg, 15mg, 20mg, 25mg, 30mg	1	30
Amphetamine (Dyanavel XR®) 2.5mg/ml Susp	8mL	240

Amphetamine (Dyanavel XR®) 5mg, 10mg, 15mg, 20mg tablets	1	30
Dextroamphetamine sulfate (Dexedrine®) 5mg cap SA	3	90
Dextroamphetamine sulfate (Dexedrine®) 10mg cap SA	6	180
Dextroamphetamine sulfate (Dexedrine®) 15mg cap SA	4	120
Dextroamphetamine sulfate 5mg tablet	3	90
Dextroamphetamine sulfate 10mg tablet	3	90
Dexmethylphenidate HCL (Focalin®) 2.5mg, 5mg, 10mg	2	60
Dexmethylphenidate HCL (Focalin XR®) 5mg, 10mg, 15mg, 20mg, 25mg, 30mg, 35mg, 40mg	1	30
Dextroamphetamine sulfate (Procentra®) 5mg/5ml solution	60	1800
Dextroamphetamine (Xelstrym™) 13.5 MG/9HR, 18 MG/9HR, 4.5 MG/9HR, 9 MG/9HR	1	30
Dextroamphetamine (Zenzedi®) 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg tablet	3	90
Dextroamphetamine (Zenzedi®) 30mg tablet	2	60
Amphetamine (Evekeo®) 5mg	3	90
Amphetamine (Evekeo®) 10mg	4	120
Amphetamine (Evekeo® ODT)	3	90

Lisdexamfetamine dimesylate (Vyvanse®) 20mg, 30mg, 40mg, 50mg, 60mg, 70mg	1	30
Methylphenidate HCL ER 24HR (Adhansia™ XR) 25mg, 35mg, 45mg, 55mg, 70mg, 85mg	1	30
Methylphenidate (Aptensio XR®)	1	30
Methylphenidate HCL (Concerta®) 18mg, 27mg, 54mg	1	30
Methylphenidate HCL (Concerta®) 36mg tablet ER	2	60
Methylphenidate HCL ER 72mg osmotic release tab	1	30
Methylphenidate (Relexxii®) tab ER osmotic release 45mg, 63mg	1	30
Methylphenidate (Daytrana patch®) 10mg/9hr, 15mg/9hr, 20mg/9hr, 30mg/9hr	1	30
Methamphetamine HCL (Desoxyn®) 5mg tablet	5	150
Methylphenidate HCL ER capsule (Jornay™ PM) 20mg, 40mg, 60mg, 80mg, 100mg	1	30
Methylpenidate HCL (Metadate CD®) 10mg, 20mg, 30mg, 40mg, 50mg, 60mg	1	30
Methylphenidate HCL (Metadate ER®) 10mg, 20mg tablet SA	3	90
Methylphenidate HCL (Methylin®) 2.5mg, 10mg chewable tablet	6	180
Methylphenidate HCL (Methylin®) 5mg chewable tablet	3	90

Methylphenidate HCL (Methylin®) 10mg/5ml	30	900
Methylphenidate HCL (Methylin®) 5mg/5ml	60	1800
Methylphenidate HCL (Ritalin®) 5mg, 10mg, 20mg	3	90
Methylphenidate HCL (Ritalin LA®) 10mg, 40mg capsule	1	30
Methylphenidate HCL (Ritalin LA®) 20mg capsule	3	90
Methylphenidate HCL (Ritalin LA®) 30mg capsule	2	60
Methylphenidate (Quillichew ER®) 20mg, 30mg	2	60
Methylphenidate (Quillichew ER®) 40mg	1	30
Methylphenidate (Quillivant XR®) 5mg/mL	12mL	360
Methylphenidate ER disintegrating tabs (Cotempla®) 8.6mg, 17.3mg, 25.9mg	1	30
Serdexmethylphenidate-dexmethylphenidate (Azstarys™)	1	30

P&T Approval Date: 2/2026

Field Name	Field Description
Prior Authorization Group Description	**Sublingual Allergenic Extracts**
Drugs	**Grastek** (timothy grass pollen allergen extract) **Odactra** (house dust mite allergen extract) **Oralair** (sweet vernal/orchard/rye/timothy/Kentucky blue grass mixed pollen allergenic extract) **Ragwitek** (Short ragweed pollen allergenic extract)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to Package Insert
Prescriber Restrictions	Prescriber is an allergist or immunologist
Coverage Duration	If all of the conditions are met, the request will be approved for a 12 month duration.
Other Criteria	**Initial authorization**: For all requests: • Requested allergenic extract is being used to treat allergic rhinitis with or without conjunctivitis • Member has had a document trial and failure of, or intolerance to, an intranasal corticosteroid (e.g. fluticasone) used in combination with at least one of the following: o Oral antihistamine (e.g. cetirizine) o Intranasal antihistamine (e.g. azelastine) o Oral leukotriene receptor antagonist (montelukast) • Patient has been prescribed (as demonstrated by pharmacy claims or documentation) injectable epinephrine Grastek: • Diagnosis has been confirmed by positive skin or in vitro testing to Timothy Grass, or cross reactive, pollen Odactra: • Diagnosis has been confirmed by either positive skin test to house dust mite allergen extract **OR** positive in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssiunus* Oralair: • Diagnosis has been confirmed by positive skin, or in vitro, testing to Sweet Vernal, Orchard, Rye, Timothy, Kentucky Blue Grass, or cross reactive, pollen

Revision/Review Date 2/2026	Ragwitek: • Diagnosis has been confirmed by positive skin, or in vitro, testing to Short Ragweed pollen **Reauthorization:** For all requests: • Member has experienced a reduction in symptoms associated with allergic rhinitis **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Teduglutide (Gattex)

Applicable Drugs:

Brand Name	Generic Name
Gattex®	teduglutide

Policy:

INITIAL CRITERIA: Teduglutide (Gattex®) is medically necessary when ALL of the following are met:

1. Diagnosis of Short Bowel Syndrome (SBS) (defined as a member left with <200 cm of functional small bowel); and
2. Currently receiving parenteral nutrition/intravenous (PN/IV) support for at least 12 consecutive months; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. Member is 1 year of age or older

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Teduglutide (Gattex®) is medically necessary when BOTH of the following are met:

1. Documentation of reduction in parenteral nutrition/intravenous (PN/IV) support from baseline (prior to initiation of teduglutide therapy) while on Gattex therapy; and
2. Prescribed by or in consultation with a gastroenterologist

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Telotristat ethyl (Xermelo)

Applicable Drugs:

Brand Name	Generic Name
Xermelo®	telotristat

Policy:

INITIAL CRITERIA: Telotristat (Xermelo®) is medically necessary when ALL of the following are met:

1. Diagnosis of carcinoid syndrome diarrhea; and
2. Member is 18 years of age or older; and
3. Diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months; and
4. Used in combination with SSA therapy; and
5. Prescribed by or in consultation with one of the following:
    1. Oncologist
    2. Endocrinologist
    3. Gastroenterologist

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Telotristat (Xermelo®) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response to Xermelo® therapy; and
2. Xermelo® will continue to be used in combination with SSA therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot])

Reauthorization duration: 2 years

P&T Approval Date: 11/2025

Title: Tolvaptan (Samsca®, Jynarque®)

Applicable Drugs:

Brand Name	Generic Name
Samsca®	Tolvaptan
Jynarque®	Tolvaptan

Policy:

Hyponatremia

INITIAL CRITERIA Tolvaptan (Samsca®) is medically necessary when ALL of the following are met:

1. Member is 18 years of age or older; and
2. Clinically significant hypervolemic or euvolemic hyponatremia and ONE of the following:
    a. Serum sodium less than 125meq/L; or
    b. Serum sodium 125-134meq/L with symptoms (i.e., nausea, vomiting, headache, lethargy, confusion, etc.); and
3. Inadequate response or inability to tolerate therapies to control hyponatremia (i.e., fluid restriction, diuretics, demeclocycline, etc.); and
4. Prescribed by or in consultation with a cardiologist, nephrologist, or endocrinologist; and
5. Brand Samsca only, inadequate response or inability to tolerate generic tolvaptan; and
6. Treatment has been initiated or re-initiated in a hospital setting prior to discharge within the past 30 days

Initial authorization duration: 30 days

REAUTHORIZATION CRITERIA Tolvaptan (Samsca®) is medically necessary when ALL of the following are met:

1. Documentation of positive clinical response; and
2. Liver function is monitored and there are no signs or symptoms of liver injury; and
3. Prescriber is aware of the risk of liver injury with use beyond 30 days

Reauthorization duration: 12 months

Autosomal dominant polycystic kidney disease

INITIAL CRITERIA Tolvaptan (Jynarque®) is medically necessary when ALL of the following are met:

1. Member is 18 years of age or older; and
2. Diagnosis of autosomal dominant polycystic kidney disease with risk of rapidly progressing kidney disease; and
3. Baseline serum transaminases and bilirubin obtained prior to initiation of therapy; and
4. Prescribed by or in consultation with nephrologist or kidney transplant specialist

Initial authorization duration: 3 months

REAUTHORIZATION CRITERIA Tolvaptan (Jynarque®) is medically necessary when ALL of the following are met:

1. ONE of the following
    a. Decline in kidney function has slowed; or
    b. Kidney pain has improved; and
2. Serum transaminase less than 3 times the upper limit of normal; and
3. Bilirubin less than 2 times upper limit of normal

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Title: Topical Hyperhidrosis Agents

Applicable Drugs:

Brand Name	Generic Name
Qbrexza™	Glycopyrronium
Sofdra™	Sofpironium

Policy:

INITIAL CRITERIA: glycopyrronium (Qbrexza®), sofpironium (Sofdra™) is medically necessary when ALL of the following are met:

1. Diagnosis of primary axillary hyperhidrosis for at least 6 months; and
2. Member is 9 years of age or greater; and
3. Prescribed by or in consultation with a dermatologist; and
4. Hyperhidrosis Disease Severity Scale grade 3 or 4; and
5. Documentation of an inadequate response (minimum 6 weeks trial), or inability to tolerate aluminum chloride (e.g. Drysol)

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: glycopyrronium (Qbrexza®), sofpironium (Sofdra™) is medically necessary when there is positive clinical response to therapy.

Reauthorization duration: 2 years

P&T Approval Date: 2/2026

Field Name	Field Description
Prior Authorization Group Description	**Transthyretin-mediated Amyloidosis Agents**
Drugs	**Preferred:** Polyneurpathy – Onpattro (patisiran), Amvuttra (vutrisiran), Wainua (eplontersen) Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), Attruby (acoramidis) **Non-preferred**: Cardiomyopathy – Amvuttra (vutrisiran) Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	**Initial Authorization**: • Regimen does not exceed FDA-approved dose/frequency • Patient has not undergone a liver or heart transplant • Requests for use multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if patient meets clinical criteria requirements for each section. **Polyneuropathy-Type** If the request is for Onpattro, Amvuttra, or Wainua: • Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by documented transthyretin variant by genotyping • One of the following: o Patient has baseline polyneuropathy disability (PND) score ≤ IIIb

Revision/Review Date:2/2026	○ Patient has a baseline FAP Stage 1 or 2 ○ Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130 • Patient has clinical signs/symptoms of neuropathy **Cardiomyopathy-Type** If the request is for Vyndaqel, Vyndamax, Attruby, or Amyuttra: • Patient has a confirmed diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis • Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging • Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms. • For Amvuttra, patient has contraindication to/or previous trial and failure or continued clinical progression with use of Vyndaqel, Vyndamax or Attruby **<u>Re-authorization (for continuing and new patients to the plan)</u>** : • Patient's regimen does not exceed FDA-approved dose/frequency for the agent • Patient has not undergone a liver or heart transplant • Requests for use multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if patient meets clinical criteria requirements for each section. • Documented positive clinical response to therapy from baseline (stabilization/slowing of disease progression, improved neurological impairment, motor functions, improved NIS score, stabilization/reduced rate of decline in 6 minute walk test, etc.) • If the request is for Vyndaqel/Vyndamax/Attruby/Amyuttra ○ Patient has continued NYHA functional class I, II, or III heart failure symptoms **<u>Continuation of Therapy Provision:</u>** Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product.

	Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Prior Authorization Group Description	**Treatment of Hereditary Angioedema (HAE)**
Drugs	**Preferred:** icatibant (Firazyr) **Non-preferred:** Berinert (C1 esterase inhibitor, human) Cinryze (C1 esterase inhibitor, human) Haegarda (C1 esterase inhibitor, human) Ruconest (C1 esterase inhibitor, recombinant) Kalbitor (ecallantide) Takhzyro (lanadelumab-flyo) Orladeyo (berotralstat) Firzyr (icatibant) Ekterly (sebetralstat) Andembry (garadacimab-gxii) Dawnzera (donidalorsen) or any newly marketed agent *If the request is for danazol, please refer to the danazol PA criteria*
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by an immunologist, allergist, rheumatologist, or hematologist

Coverage Duration	If all of the criteria are met, the request will be approved as follows:
	• Acute treatment: Initial fill + 5 refills
	• Pre-procedural prophylaxis: 1 treatment
	• Long-term prophylaxis:
	  o Initial: 6 months
	  o Reauthorization: 12 months

Other Criteria	**<u>Initial Criteria</u>**
	• Dose is appropriate for indication per compendia
	• The member is not taking ACE inhibitors, estrogen-containing oral contraceptives, or hormone replacement therapy
	• Documented diagnosis of one of the following:
	  1. HAE with deficient or dysfunctional C1INH (e.g., type I, type II, or acquired C1INH deficiency)
	  2. HAE with normal C1INH:
	  ▪ If known origin, documentation of results of confirmatory genetic test (e.g., mutations in gene for

	factor XII, angiopoietin-1, plasminogen, kininogen-1, myoferlin, heparan sulfate-glucosamine 3-*O*-sulfotransferase 6) ▪ If unknown origin (U-HAE), documentation of a prolonged trial of high-dose non-sedating antihistamines **For acute treatment (Berinert, icatibant, Kalbitor, Ruconest, Sajazir, Ekterly):** • The patient is receiving only one agent for the treatment of acute attacks. • If the request is for a non-preferred drug, the member has documented trial and failure of, or intolerance to, Berinert or icatibant **For pre-procedural prophylaxis (Cinryze, Haegarda, Orladeyo, Takhzyro, Andembry, Dawnzera):** • Documentation that patient will be undergoing a medical, surgical, or dental procedure associated with mechanical impact to the upper aerodigestive tract and anticipated date of the procedure **For long-term prophylaxis (Cinryze, Haegarda, Orladeyo, Takhzyro, Andembry, Dawnzera):** • The patient has a history of at least two severe attacks per month (e.g., swelling of the face, throat, or GI tract) or at least one laryngeal attack • The patient is only receiving one HAE medication for long-term prophylaxis • If the request is for a non-preferred drug, the member has documented trial and failure of, or intolerance to, Cinryze **<u>Reauthorization Criteria:</u>** **For acute treatment (Berinert, icatibant, Kalbitor, Ruconest, Sajazir, Ekterly):** • Dose is appropriate for indication per compendia • Documentation was submitted that the patient has clinically benefited from medication • The patient is receiving no other medications for acute treatment **For prophylaxis (Cinryze, Haegarda, Orladeyo, Takhzyro, Andembry, Dawnzera):** • Dose is appropriate for indication per compendia • Documentation was submitted that the patient has clinically benefited from prophylactic therapy as demonstrated by a reduced number of attacks • The patient is receiving no other medications for prophylaxis

Revision/Review Date: 11/2025	**Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary**

Title: Triheptanoin (Dojolvi)

Applicable Drugs:

Brand Name	Generic Name
Dojolvi™	triheptanoin

Policy:

INITIAL CRITERIA: Triheptanoin (Dojolvi) is medically necessary when ALL of the following are met:

1. Diagnosis of molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD); and
2. Will be used as a source of calories and fatty acids; and
3. Not used with any other medium-chain triglyceride (MCT) product; and
4. Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.)

Initial Authorization duration: 2 years

REAUTHORIZATION CRITERIA: Triheptanoin (Dojolvi) is medically necessary when ALL of the following are met:

1. Prescriber attests to continued need of therapy; and
2. Not used with any other medium-chain triglyceride (MCT) product; and
3. Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.)

Reauthorization duration:2 years

P&T Approval Date: 11/2025

Title: Trofinetide (Daybue)

Applicable Drugs:

Brand Name	Generic Name
Daybue™	trofinetide

Policy:

INITIAL CRITERIA: Trofinetide (Daybue™) is medically necessary when all of the following are met:

1. Diagnosis of Rett syndrome; and
2. One of the following:
    1. Presence of ALL of the following clinical signs and symptoms:
        1. A pattern of development, regression, then recovery or stabilization; and
        2. Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose; and
        3. Partial or complete loss of spoken language; and
        4. Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing; and
        5. Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait; or
    2. Molecular genetic testing confirms mutations in the MECP2 gene; and
3. Member is 2 years of age or older; and
4. Prescribed by or in consultation with one of the following:
    1. Geneticist; or
    2. Pediatrician knowledgeable in diagnosing and treating Rett Syndrome; or
    3. neurologist

Initial authorization duration: 1 year

REAUTHORIZATION CRITERIA: Trofinetide (Daybue™) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms from baseline (e.g., hand behavior, walking/standing, speech, quality of life);
2. Prescribed by or in consultation with one of the following:
    1. Geneticist; or
    2. Pediatrician knowledgeable in diagnosing and treating Rett Syndrome; or
    3. neurologist

Reauthorization duration: 1 year

P&T Approval Date: 11/2025

Title: **Urea Cycle Disorder**

Applicable Drugs:

Brand Name	**Generic Name**
Ravicti®	Gylcerol Phenylbutrate
Pheburane®	sodium phenylbutyrate oral pellets
Buphenyl®	sodium phenylbutyrate tablet/powder
Olpruva™	sodium phenylbutyrate oral suspension

Policy:

INITIAL CRITERIA Brand Buphenyl® tablet and powder, sodium phenylbutyrate oral suspension (Olpruva™), Pheburane®, glycerol phenylbutyrate (Ravicti®), generic sodium phenylbutyrate tablet and powder are medically necessary when ALL of the following are met:

1. Diagnosis of Urea Cycle Metabolism Disorder; and
2. Member has one of the following deficiencies:
    a. Carbamylphosphate synthetase (CPS), or
    b. Ornithine transcarbamylase (OTC), or
    c. Argininosuccinic acid synthetase (AS); and
3. Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene; and
4. Member cannot be managed by dietary protein restriction and/or amino acid supplementation alone; and
5. For brand Buphenyl tablet and powder, Olpruva, Ravicti only, ONE of the following:
    a. For members 18 years of age or older, inadequate response or inability to tolerate Pheburane and generic sodium phenylbutyrate tablet or powder; or
    b. For members less than 18 years of age, inadequate response or inability to tolerate Pheburane or generic sodium phenylbutyrate tablet or powder; and
6. Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, protein-free calorie supplements, arginine, etc.); and

7. Prescribed by or in consultation with a specialist experienced with the treatment of metabolic disorders

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Brand Buphenyl® tablet and powder, generic sodium phenylbutyrate tablet and powder, Pheburane®, Glycerol phenylbutyrate (Ravicti®) and sodium phenylbutyrate oral suspension (Olpruva™) is medically necessary when BOTH of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, protein-free calorie supplements, arginine, etc.)

Reauthorization duration: 2 years

P&T Approval Date: Sep-12-2024

Field Name	Field Description
Prior Authorization Group Description	**Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors**
Drugs	Austedo/Austedo XR (deutetrabenazine) Ingrezza (valbenazine) tetrabenazine (Xenazine) Any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Concurrent use of monoamine oxidase inhibitors (MAOIs)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or psychiatrist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	**Initial Authorization:** • Dose is within FDA-approved limits • Prescriber attests patient will not be receiving treatment with any other VMAT2 inhibitor **For approval for use in Tardive Dyskinesia (TD):** • Member must have clinical diagnosis of tardive dyskinesia that has persisted for the last 90 days, with documented baseline evaluation (e.g., Abnormal Involuntary Movement Scale (AIMS), the Tardive Dyskinesia Rating Scale (TDRS), etc.) • For members on antipsychotics, the antipsychotic dose(s) must have been stable for a continuous 90 day period at some point prior to the request • Prescriber has attempted at least ONE of the following strategies to manage the patient's condition, or has provided a clinical reason why NONE of the following are possible: o Reducing the dose of the drug responsible for causing dyskinesia o Discontinuing the drug responsible for causing dyskinesia o For members on first generation antipsychotics, switching to a second generation antipsychotic o Trial of benzodiazepines • For VMAT2 inhibitors other than tetrabenazine, member has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine AND o For Austedo requests:

Revision/Review Date: 2/2026	▪ Prescriber attests patient has no signs of hepatic impairment ▪ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained o For Ingrezza requests: ▪ Must be dosed at one capsule per day **For approval for use in chorea associated with Huntington's Disease (HD):** • Patient must have diagnosis of moderate to severe Huntington's with chorea, with documented baseline Total Maximal Chorea (TMC) score provided • For VMAT2 inhibitors other than tetrabenazine, member has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine AND o For Austedo requests: ▪ Prescriber attests patient has no signs of hepatic impairment ▪ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained o For Ingrezza requests: ▪ Must be dosed at one capsule per day **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (e.g., improvement from baseline in average scores on the previously submitted symptom rating scale, decrease in symptoms, etc.) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Title: Vosoritide (Voxzogo)

Applicable Drugs:

Brand Name	Generic Name
Voxzogo™	vosoritide

Policy:

INITIAL CRITERIA Vosoritide (Voxzogo™) is medically necessary when ALL of the following are met:

1. Diagnosis of achondroplasia as confirmed by ONE of the following:
    1. BOTH of the following:
        1. Member has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis); and
        2. Member has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest); or
    2. Molecular genetic testing confirmed c.1138G>A or c.1138G>C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene; and
2. Member has open epiphyses; and
3. Member did not have limb-lengthening surgery in the previous 18 months and does not plan on having limb-lengthening surgery while on Voxzogo therapy; and
4. Prescribed by or in consultation with one of the following:
    1. Clinical geneticist; or
    2. Endocrinologist; or
    3. A provider who has specialized expertise in the management of achondroplasia

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Vosoritide (Voxzogo™) is medically necessary when ALL of the following are met:

1. Member continues to have open epiphyses; and
2. Documentation of positive clinical response to therapy [e.g., improvement in annualized growth velocity (AGV) compared to baseline, or an improvement in height Z-score compared to baseline]; and
3. Prescribed by or in consultation with one of the following:
    1. Clinical geneticist; or
    2. Endocrinologist; or
    3. A provider who has specialized expertise in the management of achondroplasia

Reauthorization duration: 12 months

P&T Approval Date: 11/2025

Title: Wakefulness Promoting Agents

Applicable Drugs:

Generic name	Brand name
Pitolisant	Wakix®
Solriamfetol	Sunosi™

Policy:

Excessive daytime sleepiness in narcolepsy (Type 2)

INITIAL CRITERIA: Solriamfetol (Sunosi™) is approved when ALL of the following are met:

1. Diagnosis of excessive daytime sleepiness in narcolepsy (Type 2); and
2. Prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist; and
3. Diagnosis was confirmed by one of the following tests:
    1. Polysomnography (PSG); or
    2. Multiple sleep latency test (MSLT); and
4. Member is 18 years of age or older; and
5. Inadequate response or inability to tolerate BOTH of the following:
    1. Modafinil or armodafinil; and
    2. One of the following:
        1. One stimulant product (e.g., amphetamine, methylphenidate); or
        2. History of or potential for a substance use disorder

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Solriamfetol (Sunosi™) is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

INITIAL CRITERIA: Pitolisant (Wakix®) is approved when ALL of the following are met:

1. Diagnosis of excessive daytime sleepiness in narcolepsy (Type 2); and
2. Member is 6 years of age or older; and
3. Diagnosis was confirmed by ONE of the following tests:
    1. Polysomnography (PSG); or
    2. Multiple sleep latency test (MSLT); and
4. Prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist; and
5. Symptoms of cataplexy are absent; and
6. Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present; and
7. Inadequate response or inability to tolerate ALL of the following:
    1. Modafinil or armodafinil; and
    2. One of the following:
        1. One stimulant product (e.g., amphetamine, methylphenidate); or
        2. History of or potential for a substance use disorder; and
    3. Sunosi®

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Pitolisant (Wakix®) is re-approved when ALL of the following are met:

1. Documentation to support the efficacy associated with the current regimen; and
2. Yearly evaluation by a neurologist, psychiatrist, or sleep specialist

Reauthorization duration: 12 months

Cataplexy with narcolepsy (Type 1)

INITIAL CRITERIA: Pitolisant (Wakix®) is approved when ALL of the following are met:

1. Diagnosis of cataplexy with narcolepsy (Type 1); and
2. Member is 18 years of age or older; and
3. Symptoms of cataplexy are present; and
4. Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present; and
5. Diagnosis was confirmed by ONE of the following tests:
    1. Polysomnography (PSG); or
    2. Multiple sleep latency test (MSLT); and
6. Prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Pitolisant (Wakix®) is re-approved when ALL of the following are met:

1. Documentation to support the efficacy associated with the current regimen (including but not limited to reduction in the frequency of cataplexy attacks or an improvement in the Epworth sleepiness scale); and
2. Yearly evaluation by a neurologist, psychiatrist, or sleep specialist

Reauthorization duration: 12 months

Obstructive sleep apnea/hypopnea syndrome (OSAHS)

INITIAL CRITERIA: Solriamfetol (Sunosi™) is medically necessary when ALL of the following are met:

1. Diagnosis of obstructive sleep apnea (OSA) defined by one of the following:
    1. Member has 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; or
    2. Both of the following:
        1. Member has 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
        2. Member has symptoms of OSA (e.g., daytime sleepiness, fatigue); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a sleep specialist; and
4. Used as adjunct to standard therapy; and
5. Inadequate response or inability to tolerate ONE of the following:
    a. Modafinil or armodafinil; and
    b. One of the following:
        1. One stimulant product (e.g., amphetamine, methylphenidate); or
        2. History of or potential for a substance use disorder

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Solriamfetol (Sunosi™) is medically necessary when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

P&T Approval Date: Mar-20-2025

2. Baseline BMI is in the 95th percentile or greater standardized for age and sex prior to initiating Qsymia therapy; and

3. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Phentermine/topiramate (Qsymia) is approved when ALL of the following are met:

1. Weight loss of greater than or equal to 5% of baseline body weight; and
2. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

Reauthorization duration: 6 months

INITIAL CRITERIA: Naltrexone/bupropion (Contrave) is approved when ALL of the following are met:

1. Treatment is being requested for appetite suppression or weight loss; and
2. ONE of the following:
    1. BOTH of the following:
        1. Member is 18 years of age or older; and
        2. Baseline BMI greater than or equal to 30kg/m2 prior to initiating Contrave therapy; or
    2. ALL of the following:
        1. Member is 18 years of age or older; and
        2. Baseline BMI greater than or equal to 27kg/m2 prior to initiating Contrave therapy; and
        3. Member has a weigh-related comorbidity (e.g., hypertension, coronary artery disease, type 2 diabetes, dyslipidemia, or obstructive sleep apnea); and

Title: Wegovy for Major Adverse Cardiovascular Events Risk Reduction

Applicable Drugs:

Brand Name	Generic Name
Wegovy®	**Semaglutide**

Policy:

Major Adverse Cardiovascular Events Risk Reduction

INITIAL CRITERIA: Semaglutide (Wegovy) is medically necessary for cardiovascular events risk reduction when all of the following are met:

1. Member is 45 years of age or older; and
2. Member does not have a diagnosis of type 1 or type 2 diabetes mellitus; and
3. Submission of documentation (e.g., chart note) confirming all of the following:
    1. BMI ≥ 27 kg/m2; and
    2. Member has a history of cardiovascular disease, as evidenced by at least one of the following:
        1. Prior myocardial infarction; or
        2. Prior stroke (ischemic and hemorrhagic stroke); or
        3. Symptomatic peripheral arterial disease, as evidenced by one of the following:
            1. intermittent claudication with ankle-brachial index < 0.85, or
            2. peripheral arterial revascularization procedure, or
            3. amputation due to atherosclerotic disease; and
4. Submission of documentation (e.g., chart note) showing member is on guideline therapy management for multiple risk factors (e.g., dyslipidemia, hypertension) associated with cardiovascular disease as evidenced by the presence of all of the following:
    1. One of the following:

1. Platelet aggregation inhibitor (e.g., acetylsalicylic acid, P2Y12 receptor inhibitors) or antithrombotic medication (e.g., vitamin K antagonists, direct oral anticoagulants); or
2. Member has inability to tolerate Platelet aggregation inhibitor or anti-thrombotic medication; and

2. One of the following:
    1. Lipid-lowering medications (e.g., statins, ezetimibe, fibrate, PCSK-9 inhibitors); or
    2. Member has inability to tolerate lipid-lowering medications; and
3. One of the following:
    1. Other cardiac medications including beta blocker, angiotensin-converting-enzyme inhibitor, angiotensin-receptor blocker, and calcium channel blocker; or
    2. Member has inability to tolerate cardiac medications including beta blocker, angiotensin converting enzyme inhibitor, angiotensin-receptor blocker, and calcium channel blocker; and

5. No concurrent use of any other GLP-1 receptor agonist (e.g., Adlyxin®, Byetta®, Bydureon®, Mounjaro TM, Ozempic®, Rybelsus®, Saxenda®, Trulicity®, Victoza®)

Initial authorization duration: 1 year

REAUTHORIZATION CRITERIA: Semaglutide (Wegovy) is medically necessary for cardiovascular events risk reduction when all of the following are met:

1. Submission of documentation (e.g., chart note) showing member is on guideline therapy management for multiple risk factors (e.g., dyslipidemia, hypertension) associated with cardiovascular disease as evidenced by the presence of all of the following:
    1. One of the following:
        1. Platelet aggregation inhibitor (e.g., acetylsalicylic acid, P2Y12 receptor inhibitors) or antithrombotic medication (e.g., vitamin K antagonists, direct oral anticoagulants); or

2. Member has inability to tolerate platelet aggregation inhibitor or anti-thrombotic medication; and

2. One of the following:

    1. Lipid-lowering medications (e.g., statins, ezetimibe, fibrate, PCSK-9 inhibitors); or

    2. Member has inability to tolerate lipid-lowering medications; and

3. One of the following:

    1. Other cardiac medications including beta blocker, angiotensin-converting-enzyme inhibitor, angiotensin-receptor blocker, and calcium channel blocker; or

    2. Member has inability to tolerate cardiac medications including beta blocker, angiotensin converting enzyme inhibitor, angiotensin-receptor blocker, and calcium channel blocker; and

2. Documentation is provided confirming one of the following:

    1. Member has not experienced a cardiovascular event since starting treatment (i.e., nonfatal myocardial infarction, nonfatal stroke); and

    2. Member has experienced a non-fatal myocardial infarction or nonfatal stroke since starting treatment, but the prescriber attests the benefit outweighs risk for member to continue treatment with semaglutide (Wegovy); and

3. No concurrent use of any other GLP-1 receptor agonist (e.g., Adlyxin®, Byetta®, Bydureon®, Mounjaro™, Ozempic®, Rybelsus®, Saxenda®, Trulicity®, Victoza®)

Reauthorization duration: 1 year

P&T Approval Date: Mar-20-2025

Title: Weight Loss Medications for Obesity and Related Health Conditions

Policy: Coverage is subject to the terms, conditions, and limitations of the member's contract.

Weight loss medications are not covered under the pharmacy benefit except for members whose benefit does not exclude weight loss drugs.

This Claim Payment Policy is available to those groups that do not exclude weight loss drugs.

Major Adverse Cardiovascular Events Risk Reduction

INITIAL CRITERIA: Semaglutide (Wegovy) is approved for major adverse cardiovascular events risk reduction when ALL of the following are met:

1. Treatment is being requested to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke); and
2. Member is 18 years of age or older; and
3. Member has established cardiovascular disease defined as CAD, ACS, those with history of MI, stable or unstable angina or coronary or other arterial revascularization, prior percutaneous coronary intervention/coronary bypass surgery, stroke, TIA, carotid or other arterial stenosis, or PAD including aortic aneurysm, all of atherosclerotic origin; and
4. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
5. BMI prior to treatment is greater than or equal to 27kg/m2; and
6. Drug is not being co-administered with tirzepatide-containing products (e.g., Mounjaro, Zepbound) or GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Saxenda)

Initial authorization duration: 1 year

REAUTHORIZATION CRITERIA: Semaglutide (Wegovy) is re-approved for major adverse cardiovascular events risk reduction when ALL of the following are met:

1. Member is currently on a maintenance dose of 1.7mg or 2.4mg once weekly; and
2. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and

3. Drug is not being co-administered with tirzepatide-containing products (e.g., Mounjaro, Zepbound) or GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Saxenda)

Reauthorization duration: 1 year

Obstructive Sleep Apnea

INITIAL CRITERIA: Tirzepatide (Zepbound) is medically necessary for the treatment of moderate to severe obstructive sleep apnea (OSA) in obesity when all of the following are met:

1. Diagnosis of obstructive sleep apnea; and
2. Submission of medical records (e.g., chart notes) confirming disease is moderate to severe as defined by 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study; and
3. Member is 18 years of age or older; and
4. Submission of medical records (e.g., chart notes) confirming Body Mass Index (BMI) of greater than or equal to 30kg/m2; and
5. Submission of medical records (e.g., chart notes) confirming one of the following:
    1. Member has been evaluated and counseled on continuous positive airway pressure CPAP therapy as the preferred treatment of choice; or
    2. Member is not a candidate for CPAP therapy (e.g., upper airway anatomic abnormalities, etc.); and
6. Submission of medical records (e.g., chart notes) confirming medication will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
7. Submission of medical records (e.g., chart notes) or absence of paid claims confirming medication is not being co-administered with tirzepatide-containing products (e.g., Mounjaro) or GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Saxenda)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Tirzepatide (Zepbound) is medically necessary for the treatment of moderate to severe obstructive sleep apnea (OSA) in obesity when all of the following are met:

1. Paid claims or submission of medical records (e.g., chart notes) confirming member is currently on a maintenance dose of 10mg, 12.5mg, or 15mg once weekly; and
2. Submission of medical records (e.g., chart notes) confirming one of the following:
    1. Member has been receiving Zepbound therapy for up to 6 months and has had a weight loss of greater than or equal to 5% of baseline body weight; or
    2. Member has been receiving Zepbound therapy for greater than 6 months and is continuing to experience or maintain weight loss; and
3. Submission of medical records (e.g., chart notes) confirming medication will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
4. Submission of medical records (e.g., chart notes) or absence of paid claims confirming medication is not being co-administered with tirzepatide-containing products (e.g., Mounjaro) or GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Saxenda)

Reauthorization duration: 6 months

Short Term Weight Management

INITIAL CRITERIA: Amphetamine (Evekeo®), diethylpropion, diethylpropion ER, benzphetamine, phendimetrazine tablet, phendimetrazine ER capsule is approved when ALL of the following are met:

1. Treatment is being requested for appetite suppression or weight loss; and
2. One of the following:
    1. For diethylpropion, diethylpropion ER, phendimetrazine ER capsule only, member is 17 years of age or older; or

2. For phendimetrazine and benzphetamine only, member is 18 years of age or older; and

3. Drug will be used as adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and

One of the following:

1. Diagnosis of obesity defined as baseline BMI ≥ 30 kg/m^{2*} prior to initiation treatment; or

2. Both of the following:

    1. Baseline BMI ≥ 27 kg/m^2 prior to initiating treatment; and

    2. Member has one or more comorbidities (e.g., hypertension, coronary artery disease, type 2 diabetes mellitus, dyslipidemia, or obstructive sleep apnea); and

4. For brand Evekeo only, inadequate response or inability to tolerate generic amphetamine

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Amphetamine (Evekeo®), diethylpropion, diethylpropion ER, benzphetamine, phendimetrazine tablet, phendimetrazine ER capsule is re-approved when ALL of the following are met:

1. Weight loss of greater than or equal to 5% of baseline body weight; and

2. Drug will be used as adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavior support, community-based program)

Reauthorization duration: 6 months

Chronic Weight Management

INITIAL CRITERIA: Liraglutide (Saxenda) is approved when ALL of the following are met:

1. Treatment is being requested for appetite suppression or weight loss; and

2. ONE of the following:

1. BOTH of the following:
    1. Member is 18 years of age or older; and
    2. Baseline BMI greater than or equal to 30kg/m2 prior to initiating Saxenda therapy; or
2. ALL of the following:
    1. Member is 18 years of age or older; and
    2. Baseline BMI greater than or equal to 27kg/m2 prior to initiating Saxenda therapy; and
    3. Member has a weigh-related comorbidity (e.g., hypertension, coronary artery disease, type 2 diabetes, dyslipidemia, or obstructive sleep apnea); or
3. ALL of the following:
    1. Member is between 12 and 17 years of age; and
    2. Baseline body weight above 60kg prior to initiating Saxenda therapy; and
    3. Baseline BMI corresponding to greater than or equal to 30kg/m2 for adults (obese) by international cut-offs (e.g., Cole Criteria) prior to initiating Saxenda therapy; and

3. ONE of the following:
    1. Member is new to Saxenda therapy or has been on Saxenda therapy for less than 16 weeks; or
    2. Member is continuing Saxenda therapy and one of the following:
        1. Both of the following:
            1. Member is 18 years of age or older; and
            2. Member has been on therapy for at least 16 weeks and has had a weight loss of greater than or equal to 4% of baseline body weight; or
        2. Both of the following:
            1. Member is between 12 to 17 years of age; and
            2. Member has been on therapy for at least 16 weeks and has had a weight loss of greater than or equal to 1% of baseline body weight; and

4. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
5. Drug is not being co-administered with tirzepatide-containing products (e.g., Mounjaro, Zepbound) or GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Wegovy)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Liraglutide (Saxenda) is approved when ALL of the following are met:

1. One of the following:
    1. BOTH of the following:
        1. Member is 18 years of age and older; and
        2. ONE of the following:
            1. Member has been receiving Saxenda therapy for up to 6 months and has had a weight loss of greater than or equal to 4% of baseline body weight; or
            2. Member has been receiving Saxenda therapy for greater than 6 months and is continuing to experience or maintain weight loss; or
    2. BOTH of the following:
        1. Member is between 12 and 17 years of age; and
        2. ONE of the following:
            1. Member has been receiving Saxenda therapy for up to 6 months and has had a weight loss of at least 1% from baseline body weight or BMI; or
            2. Member has been receiving Saxenda therapy for greater than 6 months and is continuing to experience or maintain weight loss; and
2. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
3. Drug is not being co-administered with tirzepatide-containing products (e.g., Mounjaro, Zepbound) or GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Wegovy); and

4. BOTH of the following:
    1. Member has been adherent to 3 consecutive months of treatment; and
    2. Member is currently on a maintenance dose of 3mg once daily.

Reauthorization duration: 6 months

INITIAL CRITERIA: Semaglutide (Wegovy) is approved when ALL of the following are met:

1. Treatment is being requested for appetite suppression or weight loss; and
2. ONE of the following:
    1. BOTH of the following:
        1. Member is 18 years of age or older; and
        2. Baseline BMI greater than or equal to 30kg/m2 prior to initiating Wegovy therapy; or
    2. ALL of the following:
        1. Member is 18 years of age or older; and
        2. Baseline BMI greater than or equal to 27kg/m2 prior to initiating Wegovy therapy; and
        3. Member has a weigh-related comorbidity (e.g., hypertension, coronary artery disease, type 2 diabetes, dyslipidemia, or obstructive sleep apnea); or
    3. BOTH of the following:
        1. Member is between 12 and 17 years of age; and
        2. Baseline BMI is in the 95th percentile or greater standardize for age and sex prior to initiating Wegovy therapy; and
3. ONE of the following:
    1. Member is new to Wegovy therapy or has been on Wegovy therapy for less than 7 months; or
    2. Member has been on therapy for at least 7 months and has had a weight loss of greater than or equal to 5% of baseline body weight; and

4. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
5. Drug is not being co-administered with tirzepatide-containing products (e.g., Mounjaro, Zepbound) or GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Saxenda)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Semaglutide (Wegovy) is approved when ALL of the following are met:

1. ONE of the following:
    1. Member has been receiving Wegovy therapy for up to 7 months and has had a weight loss of greater than or equal to 5% of baseline body weight; or
    2. Member has been receiving Wegovy therapy for greater than 7 months and is continuing to experience or maintain weight loss; and
2. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
3. Drug is not being co-administered with tirzepatide-containing products (e.g., Mounjaro, Zepbound) or GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Saxenda); and
4. BOTH of the following:
    1. Member has been adherent to 4 consecutive months of treatment; and
    2. ONE of the following:
        1. Member is currently on a maintenance dose of 1.7mg or 2.4mg once weekly; or
        2. Member has received less than 7 months of treatment with Wegovy and is continuing to titrate to target dose of 1.7mg or 2.4mg once weekly.

Reauthorization duration: 6 months

INITIAL CRITERIA: Tirzepatide (Zepbound) is approved when ALL of the following are met:

1. Treatment is being requested for appetite suppression or weight loss; and

2. ONE of the following:
    1. BOTH of the following:
        1. Member is 18 years of age or older; and
        2. Baseline BMI greater than or equal to 30kg/m2 prior to initiating Zepbound therapy; or
    2. ALL of the following:
        1. Member is 18 years of age or older; and
        2. Baseline BMI greater than or equal to 27kg/m2 prior to initiating Zepbound therapy; and
        3. Member has a weigh-related comorbidity (e.g., hypertension, coronary artery disease, type 2 diabetes, dyslipidemia, or obstructive sleep apnea); and
3. ONE of the following:
    1. Member is new to Zepbound therapy or has been on Zepbound therapy for less than 6 months; or
    2. Member has been on therapy for at least 6 months and has had a weight loss of greater than or equal to 5% of baseline body weight; and
4. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
5. Drug is not being co-administered with tirzepatide-containing products (e.g., Mounjaro) or GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Saxenda, Wegovy)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Tirzepatide (Zepbound) is approved when ALL of the following are met:

1. ONE of the following:
    1. Member has been receiving Zepbound therapy for up to 6 months and has had a weight loss of greater than or equal to 5% of baseline body weight; or

2. Member has been receiving Zepbound therapy for greater than 6 months and is continuing to experience or maintain weight loss; and

2. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
3. Drug is not being co-administered with tirzepatide-containing products (e.g., Mounjaro) or GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Saxenda, Wegovy); and
4. BOTH of the following:
    1. Member has been adherent to 1 month of treatment; and
    2. Member is currently on a dose of 5mg, 7.5mg, 10mg, 12.5mg, or 15mg once weekly.

Reauthorization duration: 6 months

INITIAL CRITERIA: Phentermine/topiramate (Qsymia) is approved when ALL of the following are met:

1. Treatment is being requested for appetite suppression or weight loss; and
2. ONE of the following:
    1. BOTH of the following:
        1. Member is 18 years of age or older; and
        2. Baseline BMI greater than or equal to 30kg/m2 prior to initiating Qsymia therapy; or
    2. ALL of the following:
        1. Member is 18 years of age or older; and
        2. Baseline BMI greater than or equal to 27kg/m2 prior to initiating Qsymia therapy; and
        3. Member has a weigh-related comorbidity (e.g., hypertension, coronary artery disease, type 2 diabetes, dyslipidemia, or obstructive sleep apnea); or
    3. BOTH of the following:
        1. Member is between 12 and 17 years of age; and

2. Baseline BMI is in the 95th percentile or greater standardized for age and sex prior to initiating Qsymia therapy; and

3. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Phentermine/topiramate (Qsymia) is approved when ALL of the following are met:

1. Weight loss of greater than or equal to 5% of baseline body weight; and
2. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

Reauthorization duration: 6 months

INITIAL CRITERIA: Naltrexone/bupropion (Contrave) is approved when ALL of the following are met:

1. Treatment is being requested for appetite suppression or weight loss; and
2. ONE of the following:
    1. BOTH of the following:
        1. Member is 18 years of age or older; and
        2. Baseline BMI greater than or equal to 30kg/m2 prior to initiating Contrave therapy; or
    2. ALL of the following:
        1. Member is 18 years of age or older; and
        2. Baseline BMI greater than or equal to 27kg/m2 prior to initiating Contrave therapy; and
        3. Member has a weigh-related comorbidity (e.g., hypertension, coronary artery disease, type 2 diabetes, dyslipidemia, or obstructive sleep apnea); and

3. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Naltrexone/bupropion (Contrave) is approved when ALL of the following are met:

1. Weight loss of greater than or equal to 5% of baseline body weight; and
2. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

Reauthorization duration: 6 months

INITIAL CRITERIA: Orlistat (Xenical) is approved when ALL of the following are met:

1. Treatment is being requested for appetite suppression or weight loss; and
2. Member is greater than or equal to 12 years of age; and
3. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); and
4. ONE of the following:
    1. Baseline BMI greater than or equal to 30kg/m2 prior to initiating orlistat (Xenical) therapy; or
    2. BOTH of the following:
        1. Baseline BMI greater than or equal to 27kg/m2 prior to initiating orlistat (Xenical) therapy; and
        2. Member has a weight-related comorbidity (e.g., hypertension, coronary artery disease, type 2 diabetes, dyslipidemia, or obstructive sleep apnea)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Xenical or Orlistat is approved when ALL of the following are met:

1. Weight loss of greater than or equal to 5% of baseline body weight; and
2. Drug will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

Reauthorization duration: 6 months

NOTES: *For member's 12 to 17 years of age, use the Cole criteria for the corresponding BMI for member's age and sex. International Obesity Task Force BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (Cole Criteria)

Age (years)	**Body Mass Index 30kg/m2**	
	Males	Females
12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.2
14	27.63	28.57
14.5	27.98	28.87
15	28.3	29.11
15.5	28.6	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.7	29.84

P&T Approval Date: Mar-20-2025

Title: Xdemvy®

Applicable Drugs:

Brand	Generic
Xdemvy®	Lotilaner

Policy:

Lotilaner (Xdemvy®) is approved when ALL of the following are met:

1. Diagnosis of Demodex blepharitis; and
2. Member exhibits one of the following signs of Demodex infestation:
    1. Collarettes; or
    2. Eyelid margin erythema; or
    3. Eyelash anomalies (e.g., eyelash misdirection); and
3. Member is experiencing symptoms of architectural changes associated with Demodex infestation (e.g., burning, tearing, itching, foreign body sensation, eyelashes missing, eyelashes growing inward); and
4. Inadequate response or inability to tolerate tea tree-oil; and
5. Prescribed by or in consultation with one of the following:
    1. Ophthalmologist; or
    2. Optometrist

Authorization duration: 2 months

P&T Approval Date: Jul-01-2024

Field Name	Field Description
Prior Authorization Group Description	**Xolair for Asthma, Urticaria, and IgE-Mediated Food Allergy**
Drugs	Xolair (omalizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	• Use of Xolair concomitantly with another pulmonary biologic (e.g. Fasenra, Nucala, Cinqair, Dupixent, Tezspire) • Use of Xolair concomitantly with Palforzia • Use of Xolair for emergency treatment of allergic reactions, including anaphylaxis
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist, pulmonologist, or dermatologist
Coverage Duration	If all of the conditions are met, the initial and reauthorization request will be approved for up to a 6 month duration for renewal requests.
Other Criteria	****For nasal polyposis, please refer to the "Biologic Agents for Nasal Polyposis" policy**** **<u>Initial Authorization:</u>** <u>Asthma:</u> • Member has at least a 6 month history of moderate to severe asthma • The drug is being prescribed at an approved dose according to member's weight and IgE level • Member is taking maximally tolerated ICS/LABA combination in addition to a LAMA (e.g. tiotropium) for at least 3 months, or there is a documented medical reason why the member is unable to take these medications • Member's asthma is uncontrolled as defined by having one of the following: o Frequent severe exacerbations requiring two or more bursts of systemic glucocorticoids (more than three days each) in the previous year o History of serious exacerbation: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year o Airflow limitation defined as a forced expiratory volume in 1 second (FEV1) less than 80% of predicted o Poor symptom control including at least THREE of the following: ▪ Asthma Control Questionnaire (ACQ) consistently > 1.5 or Asthma Control Test (ACT) < 20 ▪ Daytime asthma symptoms more than twice per week ▪ Use of an inhaled short acting B-2 agonist to relieve asthma symptoms more than twice per week (not including use prior to exercise) ▪ Limited physical activity due to asthma symptoms ▪ Nighttime awakening due to asthma symptoms • Member has a positive immediate response on RAST test and/or skin prick test to at least 1 common allergen (e.g. dermatophagoides farinae, dermatop hagoides pteronyssinus, dog, cat, or cockroach) that is an asthma trigger (copy of results required). • Pre-treatment serum IgE levels must be greater than or equal to 30 IU/mL <u>Chronic Idiopathic Urticaria:</u>

Review/Revision Date: 2/2026	• The drug is prescribed at an approved dose • Member has at least a 6 week history of urticaria • Member requires oral corticosteroids to control symptoms • The patient remains symptomatic despite a minimum two week trial (or has medical reason for not utilizing) of two preferred second generation H1 antihistamines at the maximum tolerated dose <u>IgE-Mediated Food Allergy:</u> • Diagnosis of IgE-mediated food allergy with documented allergy to one or more of the following foods: o Peanut, milk, egg, wheat, cashew, hazelnut, or walnut • Attestation Xolair will be used in conjunction with food allergen avoidance • The drug is being prescribed at an FDA approved dose according to the member's weight and IgE level **<u>Re-Authorization:</u>** • The drug is being prescribed at an approved dose • The member has experienced a clinical benefit from medication (e.g. decrease exacerbations, reduction in use of oral steroids, decrease in skin manifestations or severe itching, improvement in pulmonary function tests, etc.) **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Yartemlea**
Drugs	Yartemlea (narsoplimab-wuug)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	2 years and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or transplant specialist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For reauthorization, the request will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	• Member is post-hematopoietic stem cell transplant (HSCT)
	• Member has a confirmed diagnosis of Transplant Associated-Thrombotic Microangiopathy (TA-TMA) based on all of the following:
	  o Platelet count < 150,000/µL
	  o Evidence of microangiopathic hemolysis (i.e., presence of schistocytes, serum lactate dehydrogenase [LDH] greater than the upper limit of normal [ULN] and/or haptoglobin less than the lower limit of normal [LLN])
	  o Renal dysfunction (i.e., doubling of serum creatinine from pretransplant)
	• Member has not received eculizumab therapy within the last three months
	• Member does not have an active infection, including clinically important localized infections
	• Member does not have a positive direct Coombs test
	• Member does not have Shiga Toxin-Producing Escherichia coli Hemolytic Uremic Syndrome (STEC-HUS)
	• Medication is prescribed at an FDA approved dose
	
	Re-Authorization:
	• Documentation or provider attestation of positive clinical response (i.e. improvement in both laboratory TMA markers [lactate dehydrogenase and platelet counts], organ function improvement, no need for transfusions)
	• Medication is prescribed at an FDA approved dose

Review/Revision Date: 05/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Zilucoplan (Zilbrysq®)

Applicable Drugs:

Brand Name	Generic Name
Zilbrysq®	Zilucoplan

Policy:

INITIAL CRITERIA: Zilucoplan (Zilbrysq®) is approved when ALL of the following are met:

1. Diagnosis of generalized myasthenia gravis (gMG); and
2. Member is 18 years of age or older; and
3. Member is anti-acetylcholine receptor (AChR) antibody positive; and
4. One of the following:
    1. Inadequate response or inability to tolerate two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus); or
    2. Both of the following:
        1. Inadequate response or inability to tolerate one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus); and
        2. Inadequate response or inability to tolerate one of the following:
            1. Chronic plasmapheresis or plasma exchange (PE); or
            2. Intravenous Immunoglobulin (IVIG); and
5. Prescribed by or in consultation with a neurologist; and
6. No concurrent use with rozanolixizumab-noli (Rystiggo), eculizumab (Soliris), ravulizumab-cwvz (Ultomiris) or efgartigimod alfa-fcab (Vyvgart, Vyvgart Hytrulo)

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Zilucoplan (Zilbrysq®) is re-approved when ALL of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Prescribed by or in consultation with a neurologist; and
3. No concurrent use with rozanolixizumab-noli (Rystiggo), eculizumab (Soliris), ravulizumab-cwvz (Ultomiris) or efgartigimod alfa-fcab (Vyvgart, Vyvgart Hytrulo)

Reauthorization duration: 12 months

P&T Approval Date: 2/2026

Prior Authorization Group Description	**Zycubo**
Drugs	Zycubo (copper histidinate)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be less than 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or specialist in the treatment of Menkes disease
Coverage Duration	If all of the criteria are met, the initial request will be approved for up to 6 months and reauthorization will be approved for up to 12 months.
Other Criteria	**Initial Authorization:** • Documented diagnosis of Menkes disease confirmed by biochemical or genetic test results • Member has an ATP7A mutation consistent with a severe Menkes disease phenotype • Prescriber attests to obtaining baseline serum copper and ceruloplasmin levels, serum electrolytes, kidney and liver function, and complete blood count prior to initiation of treatment • Medication is prescribed at an FDA approved dose **Reauthorization:** • Documentation of positive clinical benefit (i.e., improved survival, attainment of developmental milestones, physical gains, normalization of copper-related biomarkers) • Prescriber attests to monitoring serum copper and ceruloplasmin levels, serum electrolytes, kidney and liver function, and complete blood count as recommended per the manufacturer's prescribing information • Medication is prescribed at an FDA approved dose
Review/Revision Date: 05/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ophthalmic Conditions**
Drugs	Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s): • **Avastin** (bevacizumab) • **Byooviz** (ranibizumab-nuna) • **Cimerli** (ranibizumab-eqrn) Non-Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s): • **Beovu** (brolucizumab) • **Eylea** (aflibercept) • **Lucentis** (ranibizumab) • **Susvimo** (ranibizumab) • **Vabysmo** (faricimab) • **Pavblu** (aflibercept-ayyh) • **Any newly marketed agent in this class**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Eylea: approvable in pediatric patients for diagnosis of retinopathy of prematurity All other agents and indications: Approvable for adults 18 years of age and older only
Prescriber Restrictions	Ophthalmologist
Coverage Duration	If the above conditions are met, the request will be approved with a 3 month duration for initial and 12 months for renewal. Retinopathy of Prematurity: approvable for a 6 month duration for initial and renewal requests.
Other Criteria	**Avastin:** • Request is for compendia supported dosing for an ophthalmic indication **Byooviz or Cimerli:** • Request is for an FDA-approved dosing regimen **Non-Preferred VEGF Inhibitor:** • Request is for an FDA-approved dosing regimen; **AND** • Documented trial and failure with a preferred VEGF inhibitor for all FDA-approved indications OR: a medical justification for not using a preferred VEGF inhibitor (e.g. experienced a severe ADR such as hypersensitivity, arterial thromboembolism, cerebrovascular accident, raised intraocular pressure, retinal

Revision/Review Date 5/2026	detachment). • Requests for Eylea (aflibercept) may be approved for a diagnosis of retinopathy of prematurity without a trial and failure of a preferred VEGF inhibitor. Patients must have a diagnosis of retinopathy of prematurity in at least one eye with one of the following retinal findings: o ROP Zone 1 Stage 1+, 2+, 3 or 3+, or o ROP Zone II Stage 2+ or 3+, or o AP-ROP (aggressive posterior ROP) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Abatacept (Orencia®) for Injection for Intravenous Use

MEDICALLY NECESSARY:

INITIAL THERAPY
Hematopoietic Cell Transplantation

Prophylaxis of Acute Graft-Versus-Host Disease (aGVHD)
Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered for the prophylaxis of acute graft-versus-host disease (aGVHD), in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate up to four doses when all the following criteria are met:

- The individual is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or one allele–mismatched unrelated donor.
- Active or latent tuberculosis (TB) has been ruled out.
- The individual is 2 years of age or older.
- Abatacept (Orencia) will not be used in combination with other biologic disease-modifying antirheumatic drugs [bDMARDs (tumor necrosis factor [TNF] antagonists, e.g., certolizumab, adalimumab, etanercept] or Janus kinase (JAK) inhibitors (e.g., baricitinib, tofacitinib, upadacitinib).

Treatment of Chronic Graft-Versus-Host Disease (GVHD)
Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered for the treatment of chronic GVHD as additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options.

IMMUNE CHECKPOINT INHIBITOR–RELATED TOXICITIES
Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered as additional therapy for the management of the following immune checkpoint inhibitor–related (e.g., pembrolizumab [Keytruda], nivolumab [Opdivo]) autoimmune-like toxicity (also known as immune-related adverse event):

- Myocarditis, as a single agent if no improvement within 24 to 48 hours of starting high-dose methylprednisolone
- Concomitant myositis and myocarditis in combination with ruxolitinib (Jakavi)

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (pJIA)
Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered when used in individuals who have moderately to severely active pJIA. Abatacept (Orencia) injection for intravenous use may be covered as monotherapy or concomitantly with methotrexate when **all** of the following inclusion criteria are met:

- If the individual has not previously received a bDMARD to treat pJIA, abatacept (Orencia) injection for intravenous use is only eligible for coverage when the individual has a documented failure, contraindication, or intolerance to golimumab (Simponi Aria),

or there is a clinical reason that a trial of golimumab (Simponi Aria) would be otherwise inappropriate for the member.
- Active or latent TB has been ruled out.
- The individual has had an inadequate response after at least 3 months of one or more DMARDs, or the use of all DMARDs is contraindicated in the individual.
- The individual is 6 years of age or older.
- Abatacept (Orencia) will not be used in combination with other bDMARDs or JAK inhibitors.

PSORIATIC ARTHRITIS (PsA)
Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered for the treatment of active PsA. Abatacept (Orencia) injection for intravenous use may be covered as monotherapy or concomitantly with non-bDMARDs when **all** of the following inclusion criteria are met:
- If the individual has not previously received a bDMARD to treat adult rheumatoid arthritis (RA), abatacept (Orencia) injection for intravenous use is only eligible for coverage when the individual has a documented failure, contraindication, or intolerance to infliximab (Remicade), ustekinumab (Stelara), or golimumab (Simponi Aria), or there is a clinical reason that a trial of infliximab (Remicade), ustekinumab (Stelara), or golimumab (Simponi Aria) would be otherwise inappropriate for the member.
- Active or latent TB has been ruled out.
- The individual has had an inadequate response after at least 3 months of one or more DMARDs, or the use of all DMARDs is contraindicated in the individual.
- The individual is 18 years of age or older.
- Abatacept (Orencia) will not be used in combination with other bDMARDs or JAK inhibitors.

RHEUMATOID ARTHRITIS (RA)
Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered in individuals who have moderately to severely active RA. Abatacept (Orencia) injection for intravenous use may be covered as monotherapy or concomitantly with DMARDs, other than JAK inhibitors or biologic DMARDs (bDMARDs) when **all** of the following inclusion criteria are met:
- If the individual has not previously received a bDMARD to treat adult RA, abatacept (Orencia) injection for intravenous use is only eligible for coverage when the individual has a documented failure, contraindication, or intolerance to infliximab (Remicade) or golimumab (Simponi Aria), or there is a clinical reason that a trial of infliximab (Remicade) or golimumab (Simponi Aria) would be otherwise inappropriate for the member.
- Active or latent tuberculosis (TB) has been ruled out.
- The individual has had an inadequate response after at least 3 months to one or more non-bDMARDs or tumor necrosis factor (TNF) antagonists, or the use of all non-bDMARDs or TNF-antagonists is contraindicated in the individual.
- The individual is 18 years of age or older.

- Abatacept (Orencia) will not be used in combination with other bDMARDs or JAK inhibitors.

CONTINUATION THERAPY

CHRONIC GVHD

Abatacept (Orencia) injection for intravenous use is considered medically necessary for the treatment of chronic GVHD and, therefore, covered for the continuation therapy when the individual meets **both** of the following:

- Individual continues to experience chronic GVHD
- There is documentation of positive clinical response to therapy (e.g., reduction in symptoms, Global Scoring of Chronic GVHD, and steroid dose)

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS, RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS

Abatacept (Orencia) injection for intravenous use is considered medically necessary for the treatment of pJIA, RA, and PsA, and, therefore, covered for the continuation therapy when the individual meets **both** of the following:

- Individual has met the medical necessity criteria for initial therapy
- There is documentation of positive clinical response or stabilization to therapy as evidenced by at least one of the following:
    - Reduction in total active (swollen and tender) joint count from baseline
    - Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Duration of authorization: 12 months

Version Effective Date: 11/2025

Prior Authorization Group Description	**Adakveo (crizanlizumab-tmca)**
Drugs	Adakveo (crizanlizumab-tmca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	16 years of age or older
Prescriber Restrictions	Prescribed by a hematologist or provider with expertise in the treatment of sickle cell disease
Coverage Duration	If all of the criteria are met, the initial request may be approved for up to a 6-month duration. Reauthorization requests may be approved for 12 months.
Other Criteria Revision/Review Date: 02/2026	**Initial Authorization:** • Member has a confirmed diagnosis of sickle cell disease • Documentation was provided that the member has had 2 or more pain crises in the last 12 months • Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and has been compliant within the last 6 months (or a medical reason was provided why the member is unable to use hydroxyurea) • Documentation of the member's current weight • Request is for an FDA-approved dose **Reauthorization:** • Documentation has been submitted that the member has demonstrated or maintained ONE of the following changes from baseline: o Reduction in pain crises o Increased time between crises o Decrease in days hospitalized • Documentation of the member's current weight • Request is for an FDA-approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Adzynma**
Drugs	Adzynma (ADAMTS13, recombinant-krhn)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, intensive care specialist, or specialist in the treatment of rare genetic hematologic diseases
Coverage Duration	On-demand therapy: If all criteria are met, the request will be approved for 1 month. Prophylactic therapy: If all criteria are met, the initial request will be approved for 6 months. Reauthorization requests will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 5/2026
	Initial Authorization
	• Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) as confirmed by BOTH of the following:
	  o Molecular genetic testing
	  o ADAMTS13 activity <10%
	• Prescriber attestation that member has not been diagnosed with any other TTP-like disorder (i.e., microangiopathic hemolytic anemia, immune-mediated thrombotic thrombocytopenic purpura [iTTP])
	• If request is for prophylactic therapy, member must also have a history of at least one documented TTP event
	• Member's weight
	• Request is for an FDA-approved dose
	
	Reauthorization
	• Documentation of positive clinical response to therapy (i.e., improvement in acute and subacute TTP events, platelet counts, microangiopathic hemolytic anemia episodes, or clinical symptoms)
	• Member's weight
	• Request is for an FDA-approved dose
	
	Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.

Title: Agalsidase beta (Fabrazyme®) and pegunigalsidase alfa-iwxj (Elfabrio)

MEDICALLY NECESSARY:

Agalsidase beta (Fabrazyme) is considered medically necessary and, therefore, covered for individuals 2 years of age and older with Fabry disease to reduce globotriaosylceramide (GL-3) deposition in the capillary endothelium of the kidney and certain other cell types when all of the following criteria are met, including dosing and frequency:

- Diagnosis is confirmed by one of the following:
    - Deficiency of alpha-galactosidase A (α-Gal A) in plasma or peripheral leukocytes
    - Confirmation of a hemizygous pathogenic variant(s) in the galactosidase alpha (GLA) gene
- Dosing and frequency: 1 mg/kg intravenous (IV) infusion every 2 weeks
- No concomitant use of migalastat (Galafold)

Pegunigalsidase alfa-iwxj (Elfabrio) is considered medically necessary and, therefore, covered for adult individuals with confirmed Fabry disease when all of the following criteria are met, including dosing and frequency:

- Diagnosis of Fabry disease as confirmed by one the following:
    - Absence or deficiency (<5% of mean) of normal α-Gal A enzyme activity in leukocytes, dried blood spots, or serum analysis
- Molecular genetic testing demonstrating deletion or mutations in the GLA gene
- Medication is prescribed by, or in consultation with, a geneticist, endocrinologist, a metabolic disorder subspecialist, or a physician who specializes in the treatment of lysosomal storage disorders
- Presence of clinical signs and symptoms of the disease (e.g., acroparesthesias, angiokeratomas, whorls, anhidrosis/hypohidrosis, renal disease, exercise/heat/cold intolerance, etc.)
- Dosing and frequency: 1 mg/kg administered intravenously once every 2 weeks
- No concomitant use of migalastat (Galafold)

Duration of authorization: 12 months

Version Effective Date: 5/2026

Title: Alemtuzumab (Lemtrada®)

MEDICALLY NECESSARY:

Alemtuzumab (Lemtrada®) is considered medically necessary and, therefore, covered for **ONE** of the following:

- Individuals with relapsing forms of multiple sclerosis (MS), including relapsing-remitting multiple sclerosis and active secondary progressive disease, when **BOTH** the following criteria are met:
    - **ONE** of the following scenarios is met:
        - Inadequate clinical response to two or more drugs indicated for the treatment of multiple sclerosis as defined by relapse, and/or accumulating disability, and/or multiple new or enlarging of lesions of brain and/or spinal cord
        - Inadequate clinical response to one or more drugs, if individual is considered high risk for disability (e.g., the spinal MRI shows high burden of lesions, but the physical exam does not demonstrate the extent of disability)
    - Human immunodeficiency virus (HIV)-negative
- Individuals with aggressive relapsing-remitting multiple sclerosis defined as, but not limited to, accumulating disability, multiple new or enlarging of lesions of brain and/or spinal cord in the first year of illness
    - Human immunodeficiency virus (HIV)-negative

Duration of authorization: 12 months

Version Effective Date: 5/2026

Title: Alglucosidase alfa (e.g., Lumizyme®), Avalglucosidase alfa-ngpt (Nexviazyme®), Cipaglucosidase alfa-atga (Pombiliti™)

MEDICALLY NECESSARY:

ALGLUCOSIDASE ALFA (LU MIZYME)
Alglucosidase alfa (Lumizyme) is considered medically necessary and, therefore, covered for the treatment of symptomatic individuals with infantile-onset or juvenile/adult-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) when all of the following criteria are met, including dosing and frequency:

- Diagnosis is confirmed by either of the following:
    - Deficiency of acid alpha-glucosidase in leukocytes or skin fibroblasts or muscles
    - Confirmation of biallelic pathogenic variant(s) in the GAA gene
- Dosing and frequency: infants, children, adolescents and adult dosing IV: 20 mg/kg every 2 weeks

AVALGLUCOSIDASE ALFA-NGPT (NEXVIAZYME)
Avalglucosidase alfa-ngpt (Nexviazyme) is considered medically necessary and, therefore, covered for the treatment of individuals 1 year of age and older with late-onset Pompe disease (LOPD) (GAA deficiency) when all of the following criteria are met, including dosing and frequency:

- The participant has confirmed GAA enzyme deficiency from any tissue source (e.g., skin, fibroblasts, muscle, or blood) and/or two confirmed GAA gene mutations.
- Dosing and frequency:
    - ≥30 kg, the recommended dosage is 20 mg/kg (of actual body weight) every 2 weeks
    - <30 kg, the recommended dosage is 40 mg/kg (of actual body weight) every 2 weeks

CIPAGLUCOSIDASE ALFA-ATGA (POMBILITI)
Cipaglucosidase alfa-atga (Pombiliti) is considered medically necessary and, therefore, covered for the treatment of adult individuals with diagnosis of LOPD when all of the following criteria are met, including dosing and frequency:

- Diagnosis of LOPD (e.g., presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness) confirmed by either of the following:
    - Deficiency of GAA enzyme from any tissue sources (e.g., leukocytes or skin fibroblasts or muscles)
    - Confirmation of biallelic pathogenic variant(s) in the GAA gene.
- Individual's weight is greater than or equal to 40 kg
- Inadequate response or inability to tolerate an enzyme replacement therapy for Pompe disease (PD) (e.g., alglucosidase alfa or avalglucosidase alfa-ngpt)
- Medication must not be used in combination with other miglustat products (e.g., Zavesca, Yargesa)

- Dosing and frequency: 20 mg/kg (of actual body weight) administered every other week as an intravenous infusion

Note: medication must be used in combination with oral miglustat (Opfolda).

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: Allogeneic Processed Thymus Tissue-agdc (Rethymic®)

MEDICALLY NECESSARY:

Allogeneic processed thymus tissue-agdc (Rethymic) is considered medically necessary and, therefore, covered for the treatment of congenital athymia when ALL of the following criteria are met:

- The individual has a diagnosis of congenital athymia confirmed by flow cytometry demonstrating fewer than 50 naïve T-cells/mm^3 ($CD45RA^+$, $CD62L^+$) in the peripheral blood or less than 5% of total T-cells being naïve in phenotype; AND
- The individual has complete DiGeorge syndrome (cDGS) and at least one of the following:
  a. Congenital heart defect; OR
  b. Hypoparathyroidism or hypocalcemia requiring calcium replacement; OR
  c. 22q11.2 deletion syndrome; OR
  d. 10p13 hemizygosity; OR
  e. CHARGE (coloboma, heart defects, choanal atresia, growth and development retardation, genital hypoplasia, and ear anomalies including deafness) syndrome; OR
  f. clinically-supported & established pathogenic mutation(s)/variation(s) in CHD7, FOXN1, TBX1, TBX2, and/or the PAX1 genes leading to confirmed congenital athymia; AND
- The individual is NOT being treated for severe combined immunodeficiency (SCID); AND
- The individual has been screened for anti-HLA antibodies prior to receiving treatment with the requested agent; AND
- For individuals who received prior solid organ (e.g., thymus) or hematopoietic cell transplantation, the patient has undergone HLA matching of the requested agent to recipient alleles; AND
- The requested quantity does NOT exceed the maximum units, (i.e. 22,000) allowed for the duration of approval (i.e. 180 days (one treatment course per lifetime); AND
- Dosing is administered per the FDA-approval: 5,000 to 22,000 mm^2 of Rethymic surface area/m^2 recipient body surface area (BSA) administered by surgical procedure.

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: Alpha 1-Antitrypsin Therapy (e.g., Prolastin-C®, Aralast NP®, Glassia®, Zemaira®)

MEDICALLY NECESSARY:

EMPHYSEMA WITH ALPHA 1-ANTITRYPSIN DEFICIENCY
Alpha 1-antitrypsin therapy (e.g., Prolastin-C, Aralast NP, Glassia, Zemaira) is considered medically necessary and, therefore, covered for individuals 18 years of age and older who have alpha 1-antitrypsin (AAT) deficiency and clinical evidence of chronic emphysema without evidence of alpha 1-antitrypsin-associated liver disease, when all of the following criteria are met:

- The individual has a low serum concentration of alpha 1-antitrypsin (AAT) less than 80 mg/dL (radial immunodiffusion) or 50 mg/dl (nephelometry) or less than 11 uM/L (nephelometry) or less than 0.8 g/L (35 percent of normal), which is considered the threshold thought to protect against emphysema.
- The individual has a documented diagnosis of congenital alpha1-antitrypsin deficiency confirmed by one of the following:
    - Pi*ZZ, Pi*Z(null) or Pi(null)(null) protein phenotypes (homozygous)
    - Other rare AAT disease-causing alleles associated with serum alpha1-antitrypsin (AAT) level <11uM/L
- The individual has progressive panacinar emphysema with a documented rate of decline in forced expiratory volume in 1 second (FEV1).
- The individual is a non-smoker.

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: Anifrolumab-fnia (Saphnelo®)

MEDICALLY NECESSARY:

INITIAL THERAPY

Anifrolumab-fnia (Saphnelo), administered by intravenous infusion, is considered medically necessary and, therefore, covered for the treatment of adult individuals with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy* and **do not** have severe active lupus nephritis or severe active central nervous system lupus.

*Standard therapy for SLE with the use of anifrolumab-fnia (Saphnelo) includes, but is not limited to, oral corticosteroids, antimalarials (e.g., hydroxychloroquine, chloroquine), and/or immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate mofetil/mycophenolic acid) but excluding other biologic agents (including B-cell targeted therapies) and cyclophosphamide.

CONTINUATION THERAPY

Continuation of anifrolumab-fnia (Saphnelo) is considered medically necessary and, therefore, covered when all of the following criteria are met:

- All criteria under "Initial Therapy" as stated above are met.
- There is documented improvement or stabilization in disease activity due to anifrolumab-fnia (Saphnelo) treatment based on scoring instruments in SLE-associated disease area and severity (e.g., Systemic Lupus Erythematosus Disease Activity INDEX 2000 [SLEDAI-2K], British Isles Lupus Assessment Group [BILAG], and the Physician's Global Assessment [PGA] scores). It is expected that the same objective measurement scale will be used for both baseline and response to treatment.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Anti-CD19 CAR-T Immunotherapies	
Medications	Kymriah (tisagenlecleucel) Yescarta (axicabtagene ciloleucel) Tecartus (brexucabtagene autoleucel) Breyanzi (lisocabtagene maraleucel) Aucatzyl (obecabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	Patients with primary central nervous system lymphoma
Required Clinical Information	See "Other Criteria" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age for MCAL
Prescriber Restrictions	Prescriber must be an oncologist, hematologist or other appropriate specialist
Coverage Duration	If all the criteria are met, the initial request will be approved for a single treatment regimen per lifetime. • Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion • Aucatzyl: a split-dose infusion administered on day 1 and day 10 (± 2 days)
Maximum Billable Units	Variable
Other Criteria	**Initial authorization:** • Patient must not have received prior anti-CD19 CAR-T therapy. • Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines. • Patient does not have an active infection or inflammatory disorder. • Patient has a life expectancy greater than 12 weeks. • Patient will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment. • Use is supported by a labeled indication or NCCN guidelines **Leukemia** **For B-cell precursor Acute Lymphoblastic Leukemia (ALL):** • If the request is for Kymriah ○ Patient is 25 years of age or younger ○ ALL that is refractory or in second or later relapse as defined by: ▪ Second or greater bone marrow (BM) relapse or ▪ Any BM relapse after allogeneic stem cell transplant (alloSCT) and greater than or equal to 6 months from SCT at the time of tisagenlecleucel infusion or ▪ Primary refractory, defined as not achieving complete remission (CR) after 2 cycles of a standard chemotherapy regimen, or chemorefractory, defined as not achieving CR after 1 cycle of standard chemotherapy for relapsed leukemia or ▪ Philadelphia chromosome–positive ALL intolerant of or with 2 failed lines of tyrosine kinase inhibitor (TKI) therapy or if TKI therapy is contraindicated or ▪ Ineligible for alloSCT due to comorbid disease, contraindications to alloSCT conditioning regimen, lack of a suitable donor, prior SCT, or declined alloSCT after documented discussion about the role of SCT with a physician • If the request is for Tecartus or Aucatzyl ○ Patient is 18 years of age or older ○ ALL that is relapsed or refractory (one of the following):

- Primary refractory disease
- First relapse if first remission ≤ 12 months
- Relapsed or refractory disease after 2 or more lines of systemic therapy
- Relapsed or refractory disease after alloSCT, provided patient is at least 100 days after SCT at the time of Tecartus infusion or at least 3 months after SCT at the time of Aucatzyl infusion

For Chronic Lymphocytic Leukemia (CLL):

- If the request is for Breyanzi
  - Patient is 18 years of age of older
  - Patient has relapsed/refractory disease defined as failure of two or more lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor AND a B-cell lymphoma 2 (BCL-2) inhibitor

Non-Hodgkin's Lymphoma (NHL)

For Follicular Lymphoma (FL):

- If the request is for Kymriah, Breyanzi or Yescarta:
  - Patient is 18 years of age or older
  - Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy

For Large B-cell Lymphoma (LBCL), Diffuse Large B-cell Lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, follicular lymphoma grade 3B, and DLBCL arising from follicular lymphoma or indolent lymphoma:

- If the request is for Breyanzi, Kymriah, or Yescarta
  - Patient is 18 years of age or older
  - For Breyanzi ONE of the following:
    - Patient is refractory to first-line chemoimmunotherapy or relapsed within 12 months of first-line chemoimmunotherapy
    - Patient is refractory to first-line chemoimmunotherapy or relapsed after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age
    - Patient has relapsed or refractory disease after two or more lines of systemic therapy
  - For Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy
  - For Yescarta ONE of the following:
    - Patient is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy or
    - Patient has failed two or more lines of systemic therapy

For Mantle Cell Lymphoma (MCL):

- Patient is 18 years of age or older
- If the request is for Tecartus:
  - Patient has relapsed/refractory disease defined as failure of all of the following :
    - Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent
    - Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa)
- If the request is for Breyanzi:

	▪ Patient has relapsed or refractory disease who have received at least 2 prior lines of systemic therapy, including a BTK inhibitor **For Small Lymphocytic Lymphoma (SLL):** • If the request is for Breyanzi o Patient is 18 years of age or older o Patient has received at least 2 prior lines of therapy including, a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor **Re-authorization:** • Treatment exceeding a single treatment regimen per lifetime will not be authorized. o Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion o Aucatzyl: a split-dose infusion administered on day 1 and day 10 (± 2 days) If all of the above criteria are not met for initial or re-authorization, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	2/2026

Title: Atidarsagene autotemcel (Lenmeldy)

MEDICALLY NECESSARY:

Atidarsagene autotemcel (Lenmeldy) is considered medically necessary and, therefore, covered as a one-time administration for the treatment of metachromatic leukodystrophy (MLD) in individuals younger than 18 years of age when ALL of the following criteria are met:

- Individual has a confirmed diagnosis of MLD (also known as arylsulfatase A deficiency [ARSA]) as evidenced by the following biochemical and molecular markers:
    - ARSA enzyme activity below the normal range in peripheral blood mononuclear cells-leukocytes or fibroblasts OR increased urinary excretion of sulfatides; AND
    - Presence of biallelic ARSA pathogenic or likely pathogenic variation(s) of known polymorphisms identified by gene sequencing and/or deletion/duplication assessment (Note: for individuals with novel mutations, a 24-hour urine collection must show elevated sulfatide levels)
        - For the initial individual within a family with one of the below clinical classifications (i.e., a potential proband), both of the following are present:
            1. ARSA enzyme activity in leukocytes below reference values; AND
            2. Urinary sulfatide levels above reference values; AND
- Individual has confirmed clinical classification of pre-symptomatic late infantile (PSLI), presymptomatic, early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) MLD disease based on phenotypes including age and presence of applicable signs and symptoms (see Guidelines Section)
- The biologic is used as single-agent therapy (Note: not inclusive of busulfan-conditioning regimen); ANDIndividual has not received a prior allogeneic stem cell transplant (or has, but is without evidence of residual donor cells present), and is a candidate for autologous stem cell transplantation (e.g., adequate renal and hepatic function); AND
- Individual has not received other gene therapy for MLD; AND
- Individual is negative for hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotropic virus 1 and 2 (HTLV-1/HTLV-2), human immunodeficiency virus 1 and 2 (HIV-1/HIV-2), and mycoplasma infection before collection of cells for manufacturing.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Beremagene Geperpavec (Vyjuvek™)

MEDICALLY NECESSARY:

INITIATION THERAPY

Beremagene geperpavec (Vyjuvek™) is considered medically necessary and, therefore, covered in individuals 6 months and older for the treatment of wounds in individuals with dystrophic epidermolysis bullosa (DEB) when ALL of the following criteria are met:

- Individual has diagnosis of DEB; and
- Submission of medical records (e.g., chart notes, laboratory values) confirming a pathogenic variation in the collagen type VII alpha 1 chain (COL7A1) gene; and
- At least one recurrent or chronic open wound that meets all of the following criteria:
    - Adequate granulation tissue
    - Excellent vascularization
    - No evidence of active wound infection
    - No evidence or history of squamous cell carcinoma
- Individual has not had a skin graft in the past 3 months
- Beremagene geperpavec (Vyjuvek) prescribed by, or in consultation with, a dermatologist with expertise in the treatment of DEB; and
- Dosing in accordance with the US Food and Drug Administration (FDA)–approved labeling; and
- Initial authorization to be issued for no more than 6 months and no more than 26 doses

CONTINUATION THERAPY

Continued therapy with beremagene geperpavec (Vyjuvek) is considered medically necessary and, therefore, covered when ALL of the following criteria are met:

- Individual has previously been treated with beremagene geperpavec (Vyjuvek) therapy
- Individual had a positive clinical response to beremagene geperpavec (Vyjuvek) therapy (e.g., decrease in wound size, increase in granulation tissue, complete wound closure); and
- Wound(s) being treated meet all of the following criteria:
    - Adequate granulation tissue
    - Excellent vascularization
    - No evidence of active wound infection
    - No evidence or history of squamous cell carcinoma
- Individual did not have a skin graft in the past 3 months
- Beremagene geperpavec (Vyjuvek) is prescribed by, or in consultation with, a dermatologist with expertise in the treatment of DEB; and
- Dosing is in accordance with the FDA-approved labeling; and
- Reauthorization will be issued for no more than 6 months and no more than 26 doses

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Betibeglogene Autotemcel [Beti-Cel (ZYNTEGLO®)]

MEDICALLY NECESSARY:

Betibeglogene autotemcel [Beti-Cel (Zynteglo®)] is considered medically necessary and, therefore, covered for the treatment of individuals with β-thalassemia who require regular peripheral blood transfusions to maintain target hemoglobin levels when prescribed by or in consultation with a hematologist when ALL of the following criteria are also met:

- Individual has genetically confirmed diagnosis of β-thalassemia
- Individual meets one of the following:
    - Age ≥5 years and ≤50 years
    - If age <5 years, individual meets both of the following:
        - Weight ≥6 kg
        - Provider submits medical rationale that individual is anticipated to be able to provide at least the minimum number of cells required to initiate the manufacturing process
- Individual has a Karnofsky performance status (PS) of ≥80 for adults (≥16 years of age) or a Lansky PS of ≥80 for adolescents (<16 years of age)
- Individual has a clinical diagnosis of transfusion-dependent β-thalassemia (β-thalassemia major or TDT), and has documentation of one of the following in the 2 previous years
    - Receipt of ≥8 transfusions of packed red blood cells (pRBC) per year
    - Receipt of ≥100 mL/kg pRBC per year
- Individual is eligible for an allogeneic hematopoietic stem cell transplantation (HSCT)
- Individual has not received prior allogeneic HSCT or gene therapy
- Individual does not have any of the following:
    - Availability of human leukocyte antigen–identical or human leukocyte antigen–matched donor
    - T2*-weighted magnetic resonance imaging measurement of myocardial iron of less than 10 msec or other evidence of severe iron overload in the opinion of treating physician
    - Advanced liver disease (meets any one of the following)
        - Persistent aspartate transaminase, alanine transaminase, or direct bilirubin value greater than three times the upper limit of normal
        - Baseline prothrombin time or partial thromboplastin time greater than 1.5 times the upper limit of normal
        - Magnetic resonance imaging of the liver demonstrating clear evidence of cirrhosis
        - Liver biopsy demonstrating cirrhosis, any evidence of bridging fibrosis, or active hepatitis
    - Baseline estimated glomerular filtration rate less than 70 mL/min/1.73 m^2
    - History of receiving prior gene therapy or allogeneic hematopoietic stem cell transplant

- Any prior or current malignancy (with the exception of adequately treated cone-biopsied *in situ* carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin) or myeloproliferative or significant immunodeficiency disorder
- Any immediate family member (i.e., parent or siblings) with a known familial cancer syndrome (including but not limited to hereditary breast and ovarian cancer syndrome, hereditary nonpolyposis colorectal cancer syndrome and familial adenomatous polyposis)
- Active, uncontrolled hepatitis C virus or hepatitis B virus infection
- Contraindication to the use of granulocyte colony stimulating factor (G-CSF), plerixafor, busulfan, or any other medicinal products required during myeloablative conditioning, including hypersensitivity to the active substances or to any of the excipients
- A white blood cell count less than 3×10^9/L, and/or platelet count less than 100×10^9/L not related to hypersplenism

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Blinatumomab (Blincyto®)

MEDICALLY NECESSARY:

Blinatumomab (Blincyto) is considered medically necessary and, therefore, covered for individuals with acute lymphoblastic leukemia (ALL) who meet any of the following criteria, including Dosing and Frequency Requirements:

MINIMAL RESIDUAL DISEASE–POSITIVE (MRD+) DISEASE

- CD19-positive B-cell precursor acute lymphoblastic leukemia (B-ALL) in adult or pediatric individuals in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%
- Philadelphia chromosome (Ph)-negative or Ph-like B-ALL that is MRD+ in pediatric individuals as a single agent, incorporated into frontline consolidation therapy
- Ph-negative or Ph-like B-ALL that is MRD+ in pediatric individuals, after intensified consolidation therapy as a single agent
- Ph-positive B-ALL in pediatric individuals MRD+ at end of consolidation, as a single agent incorporated into frontline consolidation therapy with imatinib or dasatinib

MINIMAL RESIDUAL DISEASE–NEGATIVE (MRD-) DISEASE

- Ph-negative or Ph-like B-ALL MRD- disease in pediatric individuals as a single agent, incorporated into frontline consolidation therapy
- Ph-negative or Ph-like B-ALL MRD- disease in pediatric individuals after intensified consolidation therapy, as a single agent incorporated into continuation of frontline consolidation therapy
- Ph-positive B-ALL if refractory to TKIs in adults with MRD- as part of maintenance as a single agent alternating with POMP (mercaptopurine, vincristine, methotrexate, prednisone), if induced with inotuzumab ozogamicin + mini-hyperCVD + sequential blinatumomab

MINIMAL RESIDUAL DISEASE–NEGATIVE (MRD-) OR MRD-UNAVAILABLE DISEASE

- Consolidation as a single agent for Ph-negative B-ALL in one of the following:
    - Adolescent and Young Adult (AYA) without substantial comorbidities and adults, alternating with frontline† multiagent therapy (if not already included in a multi-part regimen)
    - AYA without substantial comorbidities and adults†, after multiagent therapy, or if multiagent therapy is contraindicated
    - Alternating with ECOG1910: cyclophosphamide, cytarabine, daunorubicin, dexamethasone, etoposide, mercaptopurine, high-dose methotrexate, pegaspargase, vincristine, rituximab for CD20-positive disease, in one of the following:
        - Frontline therapy in AYA without substantial comorbidities and adults (National Comprehensive Cancer Network [NCCN]-preferred regimen for adults aged <65 years without substantial comorbidities)

        - Refractory therapy in adults aged ≥65 years or adults with substantial comorbidities
        - Late relapse (>3 years from initial diagnosis) if regimen used in frontline in AYA without substantial comorbidities and adults
- Sequential Consolidation therapy for Ph-negative B-ALL, as a single agent after dose-adjusted HyperCVAD[§] (hyperfractionated cyclophosphamide, mesna, vincristine, doxorubicin, dexamethasone, IT methotrexate, IT cytarabine alternating with high-dose methotrexate, leucovorin, dose-adjusted cytarabine, IT methotrexate, IT cytarabine), in one of the following:
    - Frontline therapy in AYA without substantial comorbidities and adults
    - Refractory therapy in adults aged ≥65 years or adults with substantial comorbidities
    - Late relapse (>3 years from initial diagnosis) if regimen used in frontline in AYA without substantial comorbidities and adults
- Maintenance in Ph-negative ALL in AYA without substantial comorbidities and adult individuals as a single agent alternating with POMP[¶] (prednisone, vincristine, methotrexate, and mercaptopurine) in individuals with negative MRD or MRD unavailable after induction therapy with dose-adjusted HyperCVAD (hyperfractionated cyclophosphamide, mesna, vincristine, doxorubicin, dexamethasone, IT methotrexate, IT cytarabine alternating with high-dose methotrexate, leucovorin, dose-adjusted cytarabine, IT methotrexate, IT cytarabine; plus sequential blinatumomab as part of consolidation
- Frontline[†] therapy for Ph-negative B-ALL in adults with negative MRD or MRD unavailable, as a single agent in one of the following regimens:
    - Consolidation when used sequentially with inotuzumab ozogamicin + mini-hyperCVD (cyclophosphamide, vincristine, dexamethasone, inotuzumab ozogamicin alternating with cytarabine, methotrexate, inotuzumab ozogamicin)
    - Maintenance when alternating with POMP (mercaptopurine, vincristine, methotrexate, prednisone), if induced with inotuzumab ozogamicin + mini-hyperCVD + sequential blinatumomab
- Relapsed/refractory for Ph-negative B-ALL in adults with negative MRD or MRD unavailable as a single agent in one of the following regimens:
    - Consolidation when used sequentially with inotuzumab ozogamicin + mini-hyperCVD (cyclophosphamide, vincristine, dexamethasone, inotuzumab ozogamicin alternating with cytarabine, methotrexate, inotuzumab ozogamicin)
    - Maintenance when alternating with POMP (mercaptopurine, vincristine, methotrexate, prednisone), if induced with inotuzumab ozogamicin + mini-hyperCVD + sequential blinatumomab
- Sequential Consolidation therapy for Ph-positive B-ALL is adults refractory to TKIs with negative MRD or MRD unavailable disease as a single agent after inotuzumab ozogamicin + mini-hyperCVD (cyclophosphamide, vincristine, dexamethasone, inotuzumab ozogamicin alternating with cytarabine, methotrexate, inotuzumab ozogamicin)

§ Dose-adjusted HyperCVAD used with rituximab for AYA without substantial comorbidities and adults with CD20-positive disease; include methylprednisolone if CD20-positive B-ALL.
¶ POMP used with rituximab for AYA without substantial comorbidities and adults with CD20-positive disease; include methylprednisolone if CD20-positive.

PERSISTENT/RISING MINIMAL/MEASURABLE RESIDUAL DISEASE (MRD)

- Frontline† consolidation as a single agent if persistent/rising minimal/MRD for Ph-positive B-ALL in adolescent and young adult (AYA) without substantial comorbidities and adults.
- Consolidation† as a single agent for Ph-negative B-ALL in AYA without substantial comorbidities and adults with persistent/rising minimal/MRD (NCCN-preferred if have not previously received blinatumomab)

ALL REGARDLESS OF MINIMAL RESIDUAL DISEASE (MRD) DISEASE

- Ph-positive B-ALL in combination with a TKI* during frontline† induction or frontline† consolidation therapy for adolescent and young adult (AYA) without substantial comorbidities and adults (NCCN-preferred in consolidation regardless of MRD status for those who have not previously received blinatumomab)

RELAPSED OR REFRACTORY DISEASE

- Relapsed or refractory Ph-negative CD19-positive B-ALL in pediatric and adult individuals as a single agent (NCCN-preferred regimen in adults)
- Relapsed or refractory Ph-negative B-ALL in pediatric individuals
  - as a single agent
  - as a component of COG AALL1331 regimen
- Relapsed or refractory Ph-positive CD19-positive B-ALL as a single agent in pediatric and adult individuals
- Relapsed or refractory Ph-positive B-ALL in pediatric individuals who are TKI* intolerant/refractory
- Relapsed or refractory Ph-positive B-ALL in combination with a TKI* (NCCN-preferred in consolidation regardless of MRD status for those who have not previously received blinatumomab)
- Relapsed or refractory Ph-positive B-ALL in pediatric individuals in combination with dasatinib or imatinib, as a component of COG AALL1331 regimen

ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN INFANTS

- Induction in combination with Interfant regimens for infant ALL with KMT2A status (11q23) rearranged
- Infant ALL with KMT2A status (11q23) not rearranged (standard risk) as a single agent, incorporated into frontline consolidation therapy

ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN PEDIATRIC INDIVIDUALS WITH STANDARD OR HIGH-RISK DISEASE‡

- Ph-positive B-ALL with standard risk disease‡ and low MRD, as a single agent incorporated into frontline consolidation therapy with imatinib or dasatinib

- Ph-positive B-ALL with high risk disease‡ and less than complete response at end of consolidation, as a single agent incorporated into frontline consolidation therapy with imatinib or dasatinib
- Ph-positive B-ALL as consolidation therapy in combination with imatinib or dasatinib for individuals with high-risk disease‡ and less than complete response, or MRD+ at end of consolidation

*TKI options include bosutinib, dasatinib, imatinib, nilotinib, or ponatinib. Imatinib use in first line should be restricted to those who cannot tolerate broader acting
TKIs. TKI/mutation contraindications: Bosutinib - T315I, V299L, G250E, or F317L; Dasatinib - T315I/A, F317L/V/I/C or V299L; Imatinib too numerous to include; Nilotinib - T315I, Y253H, E255K/V, F359V/C/I or G250E.
† There are data to support the benefit of rituximab for CD20-positive disease in addition to chemotherapy (excluding immunotherapy) for AYA and adults aged less than 65 years without substantial comorbidities (especially if aged <60 years).
‡ Risk Stratification of ALL:

- Standard risk criteria: Aged ≥1 y to <10 y and white blood cell (WBC) count <50,000/mm^3
- High-risk criteria: Aged <1 y or ≥10 y, and/or WBC count ≥50,000/mm^3

DOSING AND FREQUENCY REQUIREMENTS
The Company reserves the right to modify the Dosing and Frequency Requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of blinatumomab (Blincyto). Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to, the US Food and Drug Administration (FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of blinatumomab (Blincyto) outside of the Dosing and Frequency Requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the precertification process. The Company reserves the right to conduct postpayment review and audit procedures for any claims submitted for blinatumomab (Blincyto).

Ph-POSITIVE OR Ph-NEGATIVE B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA (B-ALL)
For Ph-positive or Ph-Negative B-ALL, a treatment course consists of one cycle of blinatumomab (Blincyto) for induction (Cycle 1), followed by up to three additional cycles for consolidation treatment (Cycles 2–4). Each cycle consists of 4 weeks of continuous intravenous infusion followed by a 2-week treatment-free interval (total, 42 days). Do not exceed a maximum of 875 mcg, or 25 vials, per month.

Induction Cycle 1 and Consolidation Cycles 2–4

- Days 1–28
  - Weight ≥45 kg: 28 mcg/day
  - Weight <45 kg: 15 mcg/m^2/day, not to exceed 28 mcg/day
- Days 29–42: 14-day treatment-free interval

RELAPSED OR REFRACTORY B-CELL ALL

For relapsed or refractory B-ALL, a treatment course consists of up to two cycles of blinatumomab (Blincyto) for induction (Cycles 1–2), followed by three additional cycles for consolidation treatment (Cycles 3–5) and up to four additional cycles of continued therapy (Cycles 6–9). Each induction or consolidation therapy cycle consists of 4 weeks of continuous intravenous infusion followed by a 2-week treatment-free interval (total, 42 days). Each continued therapy cycle consists of 4 weeks of continuous intravenous infusion followed by an 8-week treatment-free interval (total, 84 days). Do not exceed a maximum of 875 mcg, or 25 vials, per month.

Induction Cycle 1, Days 1–7

- Weight ≥45 kg: 9 mcg/day
- Weight <45 kg: 5 mcg/m^2/day, not to exceed 9 mcg/day

Induction Cycle 1, Days 8–28

- Weight ≥45 kg: 28 mcg/day
- Weight <45 kg: 15 mcg/m^2/day, not to exceed 28 mcg/day

Induction Cycle 1, Days 29–42: 14-day treatment-free interval

Induction Cycle 2 and Consolidation Cycles 3–5

- Days 1–28
  - Weight ≥45 kg: 28 mcg/day
  - Weight <45 kg: 15 mcg/m^2/day, not to exceed 28 mcg/day
- Days 29–42: 14-day treatment-free interval

Consolidation Cycles 6–9

- Days 1–28
  - Weight ≥45 kg: 28 mcg/day
  - Weight <45 kg: 15 mcg/m^2/day, not to exceed 28 mcg/day
- Days 29–84: 56-day treatment-free interval

Duration of authorization: 12 months

Version Effective Date: 11/04/2024

Title: Botulinum Toxin Agents

MEDICALLY NECESSARY:

BOTULINUM TOXIN A
OnabotulinumtoxinA (Botox), AbobotulinumtoxinA (Dysport), IncobotulinumtoxinA (Xeomin), DaxibotulinumtoxinA-lanm (Daxxify)

OnabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), incobotulinumtoxinA (Xeomin), and daxibotulinumtoxinA-lanm (Daxxify) are considered medically necessary and, therefore, covered in adult individuals for the following indications:

- Achalasia and cardiospasm when at least one of the following criteria is met:
    - The individual whose condition has failed to respond to conventional therapy (e.g., sitting upright after eating, use of achalasia wedge for positioning, use of protein pump inhibitors or calcium channel blockers) or has a contraindication to such therapy.
    - The individual is at high risk of complications from pneumatic dilation or surgical myotomy.
    - The individual whose condition has failed to respond to prior myotomy or dilation.
    - The individual has prior dilation-induced esophageal perforation.
    - The individual has an epiphrenic diverticulum or hiatal hernia.
    - The individual is a poor surgical candidate.
- Blepharospasm in individuals 12 years of age and older
- Cervical dystonia (spasmodic torticollis)
- Chronic anal fissure with anal spasm (proctalgia fugax) with documentation that the individual has been unresponsive to one of the following:
    - Conservative treatments (e.g., sitz baths, topical anesthetics and steroids, topical glyceryl trinitrate [nitroglycerin])
    - Lateral sphincterotomy
- Prevention of chronic migraine headache or probable migraine headache occurring at least 15 days per month for at least 3 months when the duration of untreated headache on average is at least 4 hours per day. Initial treatment for botulinum toxin A is medically necessary when all of the following criteria are met:
    - A neurologist, headache specialist (headache specialist is a physician certified by the United Council for Neurologic Subspecialties [UCNS]), or pain specialist has established a diagnosis of either of the following:
        - Chronic migraine headache **OR**
        - Chronic probable migraine headache when the individual has experienced either of any two of the following pain criteria:
            - Moderate-to-severe headache pain intensity
            - Unilateral headache pain
                1. Pain aggravated by movement or pain that prohibits movement

2. Throbbing headache pain

OR

- One of the above pain criteria and one of the following associated symptoms:
  1. Nausea
  2. Sensitivity to light (photophobia) and sound (phonophobia)

- Prevention of chronic migraine headache or probable migraine headache with continued treatment will be medically necessary every 12 weeks when all of the following criteria are met:
  - The provider reports a clinically significant decrease in the frequency of headache days from the reported baseline of frequency prior to the initiation of the first series of botulinum toxin injections.
  - The re-treatment is based on continued, sustained improvement.
- Essential hand tremor in an individual whose condition has failed to respond to treatment with oral agent(s) (e.g., propranolol [Inderal], primidone [Mysoline])
- Focal dystonia or spastic dystonia: to relieve pain; to assist in posturing and walking; to increase range of motion; to assist in the outcome of physical therapy; and/or to reduce spasm, thus allowing adequate perineal hygiene after the failure of conventional treatment methods (e.g., trihexyphenidyl [Artane], tetrabenazine [Xenazine]) or if a contraindication to such treatments exist
- Hemifacial spasm
- Interstitial cystitis, as a fourth-line treatment option, after documented failure, intolerability, or contraindication to medical therapy (e.g., behavior/diet modification, pharmacologic therapy, pelvic floor physical therapy, intravesical instillations, hydrodistention)
- Isolated oromandibular dystonia
- Plantar-palmar hyperhidrosis refractory to conventional treatment options, including both topical and systemic pharmacotherapy (e.g., topical: astringents, iontophoresis; systemic: anticholinergic drugs; psychotherapy), unless clinically contraindicated AND one of the following:
  - The condition is significantly interfering with the ability to perform activities of daily living.
  - The condition is causing persistent or chronic cutaneous complications, such as skin maceration, dermatitis, secondary fungal, and microbial infections.
- Severe primary axillary hyperhidrosis that is inadequately managed by topical agents in individuals, who manifest focal, visible, severe sweating beyond physiological needs for at least 6 months without apparent cause when at least two of the following criteria are met:
  - Age of onset is younger than 25 years of age
  - Focal sweating is bilateral and relatively symmetric
  - Focal sweating does not occur during sleep
  - Family history is positive for severe primary focal hyperhidrosis

    - Hyperhidrosis significantly impairs the individual's ability to participate in daily activities
- Sialorrhea (excessive drooling) due to disabling conditions such as motor neuron disease or Parkinson disease in individuals whose condition has failed to respond to a reasonable trial of traditional therapies (i.e., anticholinergics, speech therapy, surgical therapy) or who have a contraindication to such therapy
- Spasmodic dysphonia/laryngeal dystonia (e.g., abductor dysphonia, adductor dysphonia)
- Spasticity of upper and lower limbs in adult individuals, related to any of the following conditions:
    - Cerebral palsy (CP), including use for treatment of equinus foot deformity
    - Demyelinating diseases of the central nervous system
    - Brain injury
    - Hemiplegia or paraplegia
    - Multiple sclerosis
    - Spinal cord injury
    - Stroke
- Bothersome simple motor tics (e.g., eye blinking, nose movement, head jerks) in individuals 10 years of age and older and when the benefits of treatment outweigh the risks
- Severely disabling or aggressive vocal tics in individuals 10 years of age and older when the benefits of treatment outweigh the risks
- Tourette disorder with chronic motor or vocal tics in individuals 10 years of age and older
- Urinary incontinence due to neurogenic bladder after documented failure, intolerability, or contraindication to medical therapy (e.g., pelvic floor exercises, diet/fluid management, anticholinergics, intermittent catheterization)
- Urinary incontinence due to overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency
    - The individual has a documented failure, intolerability, or contraindication to one of the following:
        - Anticholinergic medication (e.g., darifenacin [Enablex], trospium [Trosec])
        - Beta-3 adrenergic agonist (e.g., Myrbetriq or one generic alternative [solifenacin, oxybutynin tabs/tab ER/syrup, tolterodine, etc.])

OnabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), incobotulinumtoxinA (Xeomin), and daxibotulinumtoxinA-lanm (Daxxify) are considered medically necessary and, therefore, covered in pediatric individuals for the following indications:

- Spasticity of upper limbs, in pediatric individuals who are 2 years or older, related to CP or stroke when all of the following criteria are met:
    - Body weight 10 kg or over
    - Modified Ashworth Scale (MAS*) score of 2 or more in affected elbow or wrist flexors
- Spasticity of lower limbs related to CP in pediatric individuals who are 2 years or older, when all of the following criteria are met:

    - Body weight 10 kg or over
    - CP with dynamic muscle contracture of the ankle
- Strabismus in visually mature individuals (≥12 years of age) who have vision in both eyes, are unable to maintain fusion of image, and have at least one of the following:
    - Diplopia
    - Abnormal head turn
    - Asthenopia
    - Impairment of peripheral vision due to esotropia
- Chronic sialorrhea in individuals 2 years of age or older when any of the following criteria are met:
    - The individual diagnosed with a neurological disorder (e.g., CP or traumatic brain injury) and/or intellectual disability (ID) associated with chronic troublesome sialorrhea for at least 3 months.
    - The individual has an ID without neurological disorders, and the diagnosis of ID was established by a specialist, e.g., pediatrician, or by a center for developmental medicine.
    - The individual has severe drooling (modified Teachers Drooling Scale [mTDS] ≥6; clothing occasionally becomes damp)
- Neurogenic detrusor overactivity (NDO) in pediatric individuals 5 years of age and older when all of the following criteria are met:
    - The individual had an inadequate response to or was intolerant of at least one anticholinergic agent (e.g., oxybutynin [Ditropan XL, Oxytrol], tolterodine [Detrol]).
    - The individual is regularly using clean intermittent catheterization to empty the bladder
    - The individual does not have any of the following:
        - Surgery of the spinal cord within 6 months
        - Diagnosis of CP
        - Use of an indwelling catheter for urinary incontinence
        - Myasthenia gravis, Eaton-Lambert syndrome, or amyotrophic lateral sclerosis

BOTULINUM TOXIN B
RimabotulinumtoxinB (Myobloc)

RimabotulinumtoxinB (Myobloc) is considered medically necessary and, therefore, covered in adult individuals for the following indications:

- Cervical dystonia (spasmodic torticollis)
- Sialorrhea (excessive drooling) due to disabling conditions such as motor neuron disease or Parkinson disease in individuals whose condition has failed to respond to a reasonable trial of traditional therapies (i.e., anticholinergics, speech therapy, surgical therapy) or who have a contraindication to such therapy

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Burosumab-twza (Crysvita®)

MEDICALLY NECESSARY:

INITIAL THERAPY
Burosumab-twza (Crysvita®) is considered medically necessary and, therefore, covered for:

1. Individuals at least 6 months of age and older with X-linked hypophosphatemia (XLH)
2. Individuals at least 2 years of age and older with tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors (PMT) that cannot be curatively resected or localized

when all of the following criteria listed below are met:

-
- For TIO: Documented evidence of TIO associated with PMT
- Serum fibroblast growth factor 23 FGF23 (FGF23) level > 30 pg/mL
- Documentation of classic clinical features of disease (e.g., rickets, growth abnormalities [short stature or lower extremity bowing], bone pain, bone fractures)
- Fasting serum phosphorus is below the normal range for age
- Does not have renal impairment or end stage renal disease defined as a glomerular filtration rate < 30 mL/min
- Individual has or is willing to discontinue use of oral phosphate and active vitamin D analogs within one week prior to treatment initiation

CONTINUATION THERAPY
Burosumab-twza (Crysvita®) is considered medically necessary and, therefore, covered during continuation therapy for individuals at least 6 months of age and older with XLH and individuals at least 2 years of age and older with TIO associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized when all of the following criteria listed below are met:

- Normalized serum phosphate during therapy, and the absence of hyperphosphatemia
- Documented clinical improvement in the following:
    - Adult individuals --- (e.g., improvement in bone pain, enhanced mobility, radiographic evidence of improvement in osteomalacia/ fracture healing)
    - Pediatric individuals --- (e.g., enhanced height velocity, improvement in lower extremity bowing and associated abnormalities, improved walking ability, radiographic evidence of improvements of rickets/ osteomalacia/ epiphyseal healing)

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Canakinumab (Ilaris®)

MEDICALLY NECESSARY:

The following indications will be addressed in this policy. Please see the specific criteria below for the Medical Necessity criteria:

- Gout flares
- 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)
- Still's disease: adult-onset Still disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA)

GOUT FLARES

Initial Therapy

Canakinumab (Ilaris) is considered medically necessary and, therefore, covered for the treatment of gout flares in adults when the following criteria, including Dosing and Frequency Requirements, are met:

- Documentation of at least three gout flares in the previous 12 months
- Documentation of a contraindication, or inadequate response or intolerance to at least 3 months of therapy with all of the following: nonsteroidal anti-inflammatory drugs (NSAIDS), colchicine, corticosteroids
- Canakinumab (Ilaris) will not be used in combination with TNF inhibitors (e.g., adalimumab [Humira], etanercept [Enbrel], or infliximab [Remicade]) or other interleukin-1 [IL-1] blocking agents (e.g., rilonacept [Arcalyst] and anakinra [Kineret])
- Individual does not have chronic or active infection, including human immunodeficiency virus (HIV), hepatitis B, hepatitis C, or tuberculosis
- Dosing and frequency: 150 mg administered by subcutaneous injection for one dose

Continuation Therapy (after at least 12 weeks since initial therapy)

Canakinumab (Ilaris) is considered medically necessary and, therefore, covered for continuation therapy following at least 12 weeks since initial therapy when the individual meets all of the following criteria:

- Individual meets the dosing and frequency criteria outlined above
- Documented improvement in clinical signs and symptoms of gout (e.g, reduction joint pain/swelling) since the last dose, and gouty arthritis flare has recurred

PERIODIC FEVER SYNDROMES

Canakinumab (Ilaris) is considered medically necessary and, therefore, covered for any of the following indications when **all** of the corresponding criteria, including dosing and frequency requirements, are met:

Cryopyrin-Associated Periodic Syndromes (CAPS), Including Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS)

Initial Therapy

- Documented diagnosis of CAPS confirmed by molecular genetic testing that reveals pathogenic variation(s) in the *NLRP3* (also known as CIAS1) gene (e.g., variation of p.Leu353Pro or p.Leu305Pro for FCAS; variation of R260W or T348M for MWS)
- Documented presence of symptoms associated with CAPS (e.g., fever or chills, rash, joint or muscle pain, eye discomfort or redness, fatigue, headache)
- Individual is 4 years of age or older
- Canakinumab (Ilaris) will not be used in combination with TNF inhibitors (e.g., adalimumab [Humira], etanercept [Enbrel], or infliximab [Remicade]) or other IL-1–blocking agents (e.g., rilonacept [Arcalyst] and anakinra [Kineret]).
- Individual does not have chronic or active infection, including HIV, hepatitis B, hepatitis C, or tuberculosis
- Dosing and frequency: subcutaneous administration is every 8 weeks
    - For individuals with body weight greater than 40 kg, dose is 150 mg
    - For individuals with body weight 15 to 40 kg, dose is 2 mg/kg. If inadequate response, the dose may be increased to 3 mg/kg.

Continuation Therapy (After At Least 24 Weeks of Therapy)

Canakinumab (Ilaris) is considered medically necessary and, therefore, covered for continuation therapy following at least 24 weeks of therapy when the individual meets all of the following criteria:

- Individual meets the dosing and frequency criteria outlined above
- Documented reduction in total number of fever episodes and reduction in severity of other symptoms, compared to baseline

Tumor Necrosis Factor (TNF) Receptor–Associated Periodic Syndrome (TRAPS)

Initial Therapy

- Documented diagnosis of TRAPS confirmed by molecular genetic testing that reveals pathogenic variation(s) in the *TNFRSF1A* gene (e.g., R92Q, T50M, C29F, C30R/S, C33G/Y, Y38C, C52F, C55S, C70R/Y, C88R/Y)
- Documented presence of all of the following characteristics of TRAPS**:**
    - Chronic or recurrent disease (i.e., more than six fever episodes per year)
    - C-reactive protein (CRP) level of more than 10 mg/L
    - Physician's global assessment (PGA) score of 2 or higher for fever, skin rash, musculoskeletal pain, abdominal pain, and eye manifestations
- Individual is 2 years of age or older

- Canakinumab (Ilaris) will not be used in combination with TNF inhibitors (e.g., adalimumab [Humira], etanercept [Enbrel], or infliximab [Remicade]) or other IL-1–blocking agents (e.g., rilonacept [Arcalyst] and anakinra [Kineret]).
- Individual does not have chronic or active infection, including HIV, hepatitis B, hepatitis C, or tuberculosis.
- Dosing and frequency by subcutaneous injection as follows:
    - For individuals with body weight less than or equal to 40 kg, dose is 2 mg/kg administered every 4 weeks. If inadequate response, the dose can be increased to 4 mg/kg every 4 weeks.
    - For individuals with body weight greater than 40 kg, the dose is 150 mg administered every 4 weeks. If inadequate response, the dose can be increased to 300 mg every 4 weeks.

Continuation Therapy (After At Least 16 Weeks of Therapy)
Canakinumab (Ilaris) is considered medically necessary and, therefore, covered for continuation therapy following at least 16 weeks of therapy when the individual meets all of the following criteria:

- Individual meets the dosing and frequency criteria outlined above
- PGA score less than 2 for fever, skin rash, musculoskeletal pain, abdominal pain, and eye manifestations
- Documented CRP level of 10 mg/L or less, or a reduction by 70% or more from baseline

Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)*
Initial Therapy

- Documented presence of all of the following characteristics of HIDS/MKD:
    - Documented history of at least three fever episodes in a 6-month period when not receiving prophylactic treatment
    - CRP level of more than 10 mg/L
    - PGA score of 2 or higher for fever, abdominal pain, lymphadenopathy, aphthous ulcers
- Individual is 2 years of age or older
- Canakinumab (Ilaris) will not be used in combination with TNF inhibitors (e.g., adalimumab [Humira], etanercept [Enbrel], or infliximab [Remicade]) or other IL-1 blocking agents (e.g., rilonacept [Arcalyst] and anakinra [Kineret])
- Individual does not have chronic or active infection, including HIV, hepatitis B, hepatitis C, or tuberculosis
- Dosing and frequency by subcutaneous injection as follows:
    - For individuals with body weight less than or equal to 40 kg, dose is 2 mg/kg administered every 4 weeks. If inadequate response, the dose can be increased to 4 mg/kg every 4 weeks.
    - For individuals with body weight greater than 40 kg, the dose is 150 mg administered every 4 weeks. If inadequate response, the dose can be increased to 300 mg every 4 weeks.

*If genetic variation(s) in the *MVK* gene is noted in documentation, the above clinical criteria must also be met.

Continuation Therapy (after at least 16 weeks of therapy)
Canakinumab (Ilaris) is considered medically necessary and, therefore, covered for continuation therapy following at least 16 weeks of therapy when the individual meets all of the following criteria:

- Individual meets the dosing and frequency criteria outlined above
- PGA score less than 2 for fever, skin rash, musculoskeletal pain, abdominal pain, and eye manifestations
- Documented CRP level of 10 mg/L or less, or a reduction by 70% or more from baseline

Familial Mediterranean Fever (FMF)**
Initial Therapy

- Documented presence of all of the following characteristics of FMF:
    - Documented history of at least one fever episode per month
    - CRP level of more than 10 mg/L
    - PGA score of 2 or higher for fever, abdominal pain, skin rash, chest pain, arthralgia, arthritis
    - Fulfillment of Tel HaShomer diagnostic criteria for FMF as follows: two or more major symptoms, or one major plus two minor symptoms, as listed below:
        - Major Symptoms
            - Recurrent febrile episodes with serositis (peritonitis, synovitis, or pleuritis)
            - Amyloidosis of AA type without a predisposing disease
            - Favorable response to regular colchicine treatment
        - Minor Symptoms
            - Recurrent febrile episodes
            - Erysipelas-like erythema
            - FMF in a first-degree relative
- Documented contraindication, failure, or intolerance to colchicine
- Individual is 2 years of age or older
- Canakinumab (Ilaris) will not be used in combination with TNF inhibitors (e.g., adalimumab [Humira], etanercept [Enbrel], or infliximab [Remicade]) or other IL-1 blocking agents (e.g., rilonacept [Arcalyst] and anakinra [Kineret])
- Individual does not have chronic or active infection, including HIV, hepatitis B, hepatitis C, or tuberculosis
- Dosing and frequency by subcutaneous injection as follows:
    - For individuals with body weight less than or equal to 40 kg, dose is 2 mg/kg administered every 4 weeks. If inadequate response, the dose can be increased to 4 mg/kg every 4 weeks.
    - For individuals with body weight greater than 40 kg, the dose is 150 mg administered every 4 weeks. If inadequate response, the dose can be increased to 300 mg every 4 weeks.

**If genetic variation(s) in the *MEFV* gene is noted in documentation, the above clinical criteria must also be met.

Continuation Therapy (after at least 16 weeks of therapy)
Canakinumab (Ilaris) is considered medically necessary and, therefore, covered for continuation therapy following at least 16 weeks of therapy when the individual meets all of the following criteria:

- Individual meets the dosing and frequency criteria outlined above
- PGA score less than 2 for fever, skin rash, musculoskeletal pain, abdominal pain, and eye manifestations
- Documented CRP level of 10 mg/L or less, or a reduction by 70% or more from baseline

STILL DISEASE (ADULT-ONSET STILL DISEASE [AOSD], SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS [SJIA])

Initial Therapy
Canakinumab (Ilaris) is considered medically necessary and, therefore, covered for the treatment of active Still disease, including AOSD or SJIA when the following criteria, including dosing and frequency requirements, are met:

- Documented diagnosis of moderate to severely active AOSD or SJIA characterized by all of the following symptoms:
    - Chronic arthritis with two or more active joints involved (for SJIA) or four or more active joints involved (for AOSD)
    - Daily, but intermittently, high spiking fever
    - Additionally, accompanied by one or more of the following: rash, hepatosplenomegaly, lymphadenopathy, serositis
- Individual is 2 years of age or older
- There is documentation of inadequate response, intolerance, or contraindication to at least one of the following: nonsteroidal anti-inflammatory drugs (NSAIDS), corticosteroids, other disease-modifying antirheumatic drugs (DMARDs) (e.g., anakinra, methotrexate, tocilizumab, TNF inhibitors)
- Canakinumab (Ilaris) will not be used in combination with NF inhibitors (e.g., adalimumab [Humira], etanercept [Enbrel], or infliximab [Remicade]) or other IL-1 blocking agents (e.g., rilonacept [Arcalyst] and anakinra [Kineret])
- Individual does not have chronic or active infection, including HIV, hepatitis B, hepatitis C, or tuberculosis
- Dosing and frequency: for individuals with body weight 7.5 kg or above, dose is 4 mg/kg (maximum of 300 mg) administered by subcutaneous injection every 4 weeks

Continuation Therapy (after at least 32 weeks of therapy)
Canakinumab (Ilaris) is considered medically necessary and, therefore, covered for continuation therapy following at least 32 weeks of therapy when the individual meets all of the following criteria:

- Individual meets the dosing and frequency criteria outlined above
- Documented improvement or stability of AOSD or SJIA (e.g., reduction in the signs and symptoms [including number of active joints involved], and reduction in corticosteroid dose)

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Cerliponase alfa (Brineura®)

MEDICALLY NECESSARY:

INITIAL THERAPY
Cerliponase alfa (Brineura®) is considered medically necessary and, therefore, covered for pediatric individuals when all of the following criteria are met, including the dosing and frequency requirements listed in Attachment A:

- Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) disease is confirmed by either of the following:
    - TPP1 enzyme activity test indicating deficient activity in leukocytes or fibroblasts
    - Genetic test validating homozygous pathogenic variation for *TPP1*
- Score of at least 1 in the motor domain on the CLN2 Clinical Rating Scale

CONTINUATION THERAPY
Cerliponase alfa (Brineura) is considered medically necessary and, therefore, covered for continuation therapy when the pediatric individual meets all of the following criteria:

- Score of at least 1 in the motor domain on the CLN2 Clinical Rating Scale

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: Coagulation Factors

MEDICALLY NECESSARY:

HEMOPHILIA A (FACTOR VIII DEFICIENCY)
The following coagulation factors are considered medically necessary and, therefore, covered for the prevention and/or treatment of bleeding episodes in individuals with hemophilia A (factor VIII deficiency):

- Human preparations: Alphanate, Koate-DVI, Hemofil M, Humate-P, and Wilate
- Recombinant preparations: Advate, Adynovate, Afstyla, Altuviiio, Eloctate, Esperoct, Jivi, , Kovaltry, Novoeight, Nuwiq, Recombinate, and Xyntha**/**Xyntha Solofuse
- Human monoclonal antibody: Hemlibra, Hympavzi

HEMOPHILIA B (FACTOR IX DEFICIENCY)
The following coagulation factors are considered medically necessary and, therefore, covered for the prevention and/or treatment of bleeding episodes in individuals with hemophilia B (factor IX deficiency):

- Human preparations: Alphanine SD, Profilnine
- Recombinant preparations: Alprolix, BeneFIX, Idelvion, Ixinity, Rebinyn, and Rixubis
- Human monoclonal antibody: Hympavzi

HEMOPHILIA WITH INHIBITORS TO FACTORS VIII OR IX
The following coagulation factors are considered medically necessary and, therefore, covered for the prevention and/or treatment of bleeding episodes in individuals with hemophilia with inhibitors to factors VIII or IX:

- Human and recombinant factors VIII or IX (see hemophilia A and B above)
- FEIBA (human plasma–derived activated prothrombin complex concentrate [APCC])
- Recombinant activated coagulation factor VIIa (e.g., NovoSevenRT, Sevenfact)
- Human monoclonal antibody (e.g., emicizumab-kxwh [Hemlibra]) for hemophilia with inhibitors to factor VIII

FACTOR I DEFICIENCY, ACQUIRED
Fibryga (fibrinogen concentrate [Human]) is considered medically necessary and, therefore, covered for the treatment of bleeding episodes in individuals with acquired fibrinogen deficiency (AFD).

FACTOR I DEFICIENCY, CONGENITAL
Fibryga and RiaSTAP (fibrinogen concentrate [Human]) are considered medically necessary and, therefore, covered for the treatment of bleeding episodes in individuals with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. **NOTE:** See EXPERIMENTAL/INVESTIGATIONAL section regarding dysfibrinogenemia.

FACTOR VII DEFICIENCY, CONGENITAL
NovoSeven RT (recombinant-activated coagulation factor VIIa) is considered medically necessary and, therefore, covered for the prevention and/or treatment of bleeding episodes in individuals with congenital factor VII deficiency.

FACTOR VIII DEFICIENCY, ACQUIRED
The following coagulation factors are considered medically necessary and, therefore, covered for the prevention and/or treatment of bleeding episodes in individuals with acquired factor VIII deficiency:

- Factor VIII concentrates, including Obizur
- Alphanate (antihemophilic factor VIII/von Willebrand factor complex [human])
- NovoSeven RT (recombinant-activated coagulation factor VIIa)
- FEIBA (human plasma–derived APCC)

FACTOR X DEFICIENCY, ACQUIRED OR CONGENITAL
Coagadex is considered medically necessary and, therefore, covered for the prevention and/or treatment of bleeding episodes in individuals with factor X deficiency

FACTOR XIII DEFICIENCY, ACQUIRED OR CONGENITAL
The following coagulation factors are considered medically necessary and, therefore, covered for the prevention and/or treatment of bleeding episodes in individuals with acquired or congenital factor XIII deficiency:

- Corifact (factor XIII concentrate [Human])
- Tretten (factor XIII A-subunit [Recombinant])

GLANZMANN'S THROMBASTHENIA (GLYCOPROTEIN COMPLEX IIb/IIIa DEFICIENCY)
NovoSeven RT (recombinant-activated coagulation factor VIIa) is considered medically necessary and, therefore, covered for the prevention and/or treatment of bleeding episodes in individuals with Glanzmann’s thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets.

VON WILLEBRAND DISEASE
The following coagulation factors are considered medically necessary and, therefore, covered for the prevention and/or treatment of bleeding episodes in individuals with von Willebrand disease when the use of desmopressin (1-desamino-8-D-arginine vasopressin [DDAVP]) is known or suspected to be ineffective or contraindicated:

- Human preparations: Alphanate, Humate-P, Wilate
- Recombinant preparation: Vonvendi

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Collagenase clostridium histolyticum (Xiaflex ®)

MEDICALLY NECESSARY:

COLLAGENASE CLOSTRIDIUM HISTOLYTICUM (XIAFLEX)

Dupuytren's Contracture with a Palpable Cord
Collagenase clostridium histolyticum (Xiaflex) injection is considered medically necessary and, therefore, covered for the treatment of adult individuals with
a diagnosis of Dupuytren's contracture with a palpable cord when all of the following criteria are met:

- The individual has a finger flexion contracture with a palpable cord in a metacarpophalangeal joint or a proximal interphalangeal joint.
- The contracture is at least 20 degrees.
- The individual had a positive tabletop test, defined as the inability to simultaneously place the affected finger(s) and palm flat against a table.

Peyronie's Disease
Collagenase clostridium histolyticum (Xiaflex) injection is considered medically necessary and, therefore, covered for the treatment of adult individuals with a diagnosis of Peyronie's disease when all of the following criteria are met:

- The individual has a palpable plaque inside the penis.
- The individual has curvature deformity of at least 30 degrees.
- The is individual is experiencing pain or sexual dysfunction.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Crovalimab-akkz (Piasky)

MEDICALLY NECESSARY:

PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)
Crovalimab-akkz (PiaSky) is considered medically necessary and, therefore, covered for the treatment of PNH in adult and pediatric (13 years and older) individuals, when all of the following criteria are met, including dosing and frequency:

Initial Criteria

- The individual has body weight 40 kilograms or more
- Flow cytometry demonstrates one of the following:
    - At least 10% PNH type III red cells
    - Greater than 50% of glycosylphosphatidylinositol-anchored proteins (GPI-AP)–deficient polymorphonuclear (PM) cells
- The individual exhibits clinical manifestations of disease (e.g., lactate dehydrogenase [LDH] > 1.5 upper limit of normal [ULN], thrombosis, renal dysfunction, pulmonary hypertension, dysphagia)
- The individual is transfusion dependent due to PNH.
- The individual does not have unresolved *Neisseria meningitidis* infection.
- The individual is vaccinated against *N. meningitidis,* unless risk of delaying crovalimab-akkz (PiaSky) outweighs the risks of developing meningococcal infection.
- Crovalimab-akkz (PiaSky) will not be used in combination with another complement inhibitor (e.g., Empaveli, Fabhalta, Soliris, Ultomiris) for the treatment of PNH.
- Dosing and frequency for crovalimab-akkz (PiaSky) are according to FDA labeling

Continuation Criteria
Crovalimab-akkz (PiaSky) is considered medically necessary and, therefore, covered for continuation therapy, when documentation is provided of positive clinical response (e.g., reduction in hemolysis manifested by stabilization of hemoglobin levels and reduction in transfusions from baseline at initiation).

Duration of authorization: 12 months

Version Effective Date:05/2026

Title: Delandistrogene moxeparvovec (delandistrogene moxeparvovec-rokl; Elevidys®)

Policy

Coverage is subject to the terms, conditions, and limitations of the member's contract.

BENEFIT EXCLUSION

Delandistrogene moxeparvovec-rokl (Elevidys®) is a benefit contract exclusion for most plans, and, therefore, not eligible for reimbursement consideration. Individual benefits must be verified.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Field Name	Field Description
Prior Authorization Group Description	**Dendritic Cell Tumor Peptide Immunotherapy**
Drugs	Provenge (sipuleucel-T)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Small cell/neuroendocrine prostate cancer
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be an oncologist or urologist
Coverage Duration	If all the criteria are met, the request will be approved for 3 doses per lifetime

Other Criteria
 	
Revision/Review Date 5/2026
	Initial Authorization:
	• Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history)
	  o Evidenced by soft tissue and/or bony metastases
	  o Patient does NOT have
	  ▪ M0CRPC (defined as CRPC whose only evidence of disseminated disease is an elevated serum PSA) is not authorized
	  ▪ Visceral metastases (e.g. liver, lung, adrenal, peritoneal, brain)
	• Patient is not currently being treated with systemic immunosuppressants (e.g. chemotherapy, corticosteroids) or, if the patient is being treated with immunosuppressants, the prescriber has provided a valid medical reason for combination therapy
	• Eastern Cooperative Oncology Group (ECOG) score 0-1
	• Serum testosterone <50 ng/dL (e.g. castration levels of testosterone)
	• Predicted survival of at least six months
	Reauthorization:
	• Treatment exceeding 3 doses per lifetime will not be authorized
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Title: Denosumab (Prolia®, Xgeva®) and related biosimilars, and Romosozumab-aqqg (Evenity®)

MEDICALLY NECESSARY:

DENOSUMAB (PROLIA) AND RELATED BIOSIMILARS

Initial Therapy

Denosumab (Prolia) and related biosimilars, administered subcutaneously by a professional provider, are considered medically necessary and, therefore, covered for the following indications:

- Treatment of postmenopausal individuals with a documented diagnosis of osteoporosis (defined as T-score less than or equal to -2.5 for osteoporosis or documented history of an osteoporotic non-collision fracture [e.g., vertebral, hip, nonvertebral]) when **EITHER** of the criteria listed below is met:
    - The individual has multiple risk factors for fracture (e.g., endocrine disorders, gastrointestinal disorders, use of medications associated with low bone mass or bone loss [e.g., daily systemic glucocorticoids and expected to continue for at least three months])
    - The individual has or has had **ONE** of the following:
        - Documented intolerance to at least one other osteoporosis medicine (e.g., oral or injectable bisphosphonates, estrogens) due to side effects
        - Documented inadequate response from at least one other available osteoporosis medicine (e.g., oral or injectable bisphosphonates, estrogens) after a trial of 12 months
        - A severely deteriorated condition indicating that the osteoporosis is so significant that a trial of bisphosphonates is not medically warranted (e.g., very low T-score [less than -3.0], high risk for falls/history of injurious falls, very high fracture probability by fracture risk assessment tool [FRAX] [e.g., major osteoporosis fracture >30 percent, hip fracture >4.5 percent])
        - Documented moderate to severe renal insufficiency (glomerular filtration rate [GFR] 30 to 35 mL/min or less)
- Treatment of males (genotypic males) 50 years of age and older with a documented diagnosis of osteoporosis (defined as T-score less than or equal to -2.5 for osteoporosis or documented history of an osteoporotic non-collision fracture [e.g., vertebral, hip, nonvertebral]) when **EITHER** of the criteria listed below are met:
    - The individual has multiple risk factors for fracture (e.g., endocrine disorders, gastrointestinal disorders, use of medications associated with low bone mass or bone loss [e.g., daily systemic glucocorticoids and expected to continue for at least three months])
    - The individual has or has had **ONE** of the following:
        - Documented intolerance to at least one other osteoporosis medicine (e.g., oral or injectable bisphosphonates) due to side effects

        - Documented inadequate response from at least one other available osteoporosis medicine (e.g., oral or injectable bisphosphonates) after a trial of 12 months
        - A severely deteriorated condition indicating that the osteoporosis is so significant that a trial of bisphosphonates is not medically warranted (e.g., very low T-score [less than -3.0], high risk for falls/history of injurious falls, very high fracture probability by FRAX [e.g., major osteoporosis fracture >30 percent, hip fracture >4.5 percent])
        - Documented moderate to severe renal insufficiency (glomerular filtration rate [GFR] 30 to 35 mL/min or less)
- Treatment of individuals less than 50 years of age with documented diagnosis of glucocorticoid-induced osteoporosis **AND** history of an osteoporotic non-collision fracture contributing to high risk for fracture when **ALL** of the following criteria are met:
    - The individual is initiating or continuing daily systemic glucocorticoids and expected to continue for at least three months
    - The individual is not pregnant and is using effective contraception during therapy
    - The individual has or has had **ONE** of the following:
        - Documented intolerance to at least one other osteoporosis medicine (e.g., oral or injectable bisphosphonates, estrogens) due to side effects
        - Documented inadequate response from at least one other available osteoporosis medicine (e.g., oral or injectable bisphosphonates, estrogens) after a trial of 12 months
        - A severely deteriorated condition indicating that the osteoporosis is so significant that a trial of bisphosphonates is not medically warranted (e.g., very low T-score [less than -3.0], high risk for falls/history of injurious falls, very high fracture probability by FRAX [e.g., major osteoporosis fracture >30 percent, hip fracture >4.5 percent])
        - Documented moderate to severe renal insufficiency (glomerular filtration rate [GFR] 30 to 35 mL/min or less)
- Treatment of osteopenia (defined as T-score less than -1.0, but greater than -2.5), when the individual meets **EITHER** of the following criteria:
    - Receiving adjuvant aromatase inhibitor therapy for breast cancer (either invasive [with lobular, mixed, metaplastic, ductal/NST, micropapillary, pure tubular, pure mucinous, pure cribriform, encapsulated or solid papillary carcinoma, other rare forms, adenoid cystic and other salivary carcinomas, secretory carcinoma, rare low-grade forms of metaplastic carcinoma histology, ductal carcinoma in situ] or inflammatory) (assure that the individual is not pregnant and is using effective contraception during therapy)
    - Receiving androgen deprivation therapy for nonmetastatic prostate cancer
- For males (genotypic males) 50 years of age and older or postmenopausal individuals with a diagnosis of osteopenia (defined as T-score less than -1.0 but greater than -2.5) when the individual meets **BOTH** of the following criteria:
    - The individual has or has had **ONE** of the following:

        - Documented intolerance to at least one other osteoporosis medicine (e.g., oral or injectable bisphosphonates, estrogens) due to side effects
        - Documented inadequate response from at least one other available osteoporosis medicine (e.g., oral or injectable bisphosphonates, estrogens) after a trial of 12 months
        - Documented moderate to severe renal insufficiency (glomerular filtration rate [GFR] 30 to 35 mL/min or less) not receiving dialysis or diagnosed with stage 5 kidney disease
    - The individual has **ONE** of the following:
        - US-adapted World Health Organization (WHO) 10-year probability of a hip fracture based on the Fracture Risk Assessment tool (FRAX) assessment is three percent or more
        - WHO 10-year fracture probability of any major osteoporosis-related fracture based on the FRAX assessment is 20 percent or more

Continuation Therapy

Denosumab (Prolia) and related biosimilars are considered medically necessary and, therefore, covered for continuation therapy unless the individual has a documented intolerance, contraindication, or nonresponse to the drug.

ROMOSOZUMAB-AQQG (EVENITY)
Romosozumab-aqqg (Evenity), administered subcutaneously by a professional provider, for a limited duration of 12 monthly doses is considered medically necessary and, therefore, covered for the following indications:

- Treatment of postmenopausal individuals with a documented diagnosis of osteoporosis (defined as T-score less than or equal to -2.50 for osteoporosis or documented history of an osteoporotic non-collision fracture [e.g., vertebral, hip, nonvertebral]) when **BOTH** of the criteria listed below are met:
    - The individual has multiple risk factors for fracture (e.g., endocrine disorders, gastrointestinal disorders, use of medications associated with low bone mass or bone loss [e.g., daily systemic glucocorticoids and expected to continue for at least three months])
    - The individual has or has had documented intolerance due to side effects, or inadequate response after a trial of 12 months to Receptor Activator of Nuclear factor Kappa-B (RANK) ligand inhibitor (e.g., denosumab [Prolia] and related biosimilars)
- For individuals with a severely deteriorated condition indicating that the osteoporosis is so significant (i.e., T-score less than -3.5 or a T-score less than -2.5 with a history of fragility fractures) that a trial of bisphosphonates and RANK ligand inhibitor (e.g., denosumab [Prolia] and related biosimilars) is not medically warranted.

Romosozumab-aqqg (Evenity) is not recommended for individuals with a history of a myocardial infarction or stroke within the preceding year; (consider benefit versus risk in individuals with other cardiovascular risk factors).

Note:
The anabolic effect of romosozumab wanes after 12 monthly doses of therapy. Therefore, the duration of romosozumab-aqqg (Evenity) use is limited to 12 monthly doses. If osteoporosis therapy remains warranted after medically necessary romosozumab-aqqg (Evenity), continued therapy with an anti-resorptive agent (e.g., denosumab [Prolia] and related biosimilars, alendronate [Fosamax, Binosto]) should be considered.

DENOSUMAB (XGEVA) AND RELATED BIOSIMILARS
Denosumab (Xgeva) and related biosimilars, administered subcutaneously by a professional provider, are considered medically necessary and, therefore, covered for the following indications (assure that the individual is not pregnant and is using effective contraception during therapy):

- Prevention of skeletal-related events (i.e., pathologic fracture, need for radiation therapy to bone, need for surgery to bone, or spinal cord compression) in individuals with bone metastases from solid tumors. These include, but are not limited to, the following malignancy-related conditions:
    - Invasive (with lobular, mixed, metaplastic, ductal/NST, micropapillary, pure tubular, pure mucinous, pure cribriform, encapsulated or solid papillary carcinoma, other rare forms, adenoid cystic and other salivary carcinomas, secretory carcinoma, rare low-grade forms of metaplastic carcinoma histology) or inflammatory breast cancer:
        - Used with calcium and vitamin D supplementation in addition to chemotherapy or endocrine therapy for bone metastases in individuals with expected survival of three months or greater and adequate renal function
    - Non-small cell lung cancer (with squamous cell carcinoma, adenocarcinoma [with mixed subtypes], or large cell carcinoma histology):
        - Supportive therapy in individuals with bony metastases
    - Prostate cancer:
        - Individuals with bone metastases from castration-resistant prostate cancer (metastatic prostate cancer that has stopped responding to androgen deprivation therapy and continues to grow) with creatinine clearance greater than 30 mL/min (National Comprehensive Cancer Network [NCCN] preferred)
    - Thyroid cancer:
        - Individuals with bone metastases from any of the following thyroid cancer types: follicular, Hurthle cell/oncocytic, medullary, papillary carcinoma
        - Palliative care for bone metastases in individuals with anaplastic carcinoma
    - Kidney cancer (with either clear cell or non-clear cell histology):
        - As a component of best supportive care for individuals with bony metastases

- Prevention of skeletal-related events (i.e., pathologic fracture, need for radiation therapy to bone, need for surgery to bone, or spinal cord compression) in individuals with multiple myeloma
    - Used in combination with primary myeloma therapy. NCCN preferred agent in individuals with renal insufficiency
- Treatment of adult and skeletally mature (i.e., at least one mature long bone [e.g., closed epiphyseal growth plate of the humerus]) adolescent individuals with a giant cell tumor of the bone (GCTB) in the following circumstances:
    - When the GCTB is unresectable or where surgical resection is likely to result in severe morbidity
    - Treatment as a single agent (NCCN preferred) or combined with serial embolization, (NCCN preferred) and/or radiation therapy for resectable disease with unacceptable morbidity and/or unresectable axial lesions for individuals with localized disease, metastases at presentation, or disease recurrence
    - Treatment as a single agent (NCCN preferred) for unresectable metastatic disease at presentation, unresectable metastatic recurrence, or considered prior to surgery for resectable local recurrence
- Treatment of individuals with hypercalcemia of malignancy (i.e., albumin-corrected serum calcium level greater than 12.5 mg/dL [3.1 mmol/L]) refractory to bisphosphonate therapy
- Treatment of individuals with systemic mastocytosis as a second-line therapy for osteopenia/osteoporosis in individuals with bone pain not responding to bisphosphonates or for individuals who are not candidates for bisphosphonates because of renal insufficiency.

Duration of authorization: 12 months

Version Effective Date: 2/2026

Title: Dofetilide (Tikosyn®) Use in the Inpatient Setting

MEDICALLY NECESSARY:

An inpatient admission for the initiation, dose escalation or reinitiation of dofetilide (Tikosyn) is considered medically necessary and, therefore, covered for either of the following indications:

- For conversion of atrial fibrillation (AF) and atrial flutter (AFL) (AF/AFL) to normal sinus rhythm (NSR)
- For the maintenance of NSR (delay in time recurrence of AF/AFL) in individuals with AF/AFL of greater than 1 week's duration who have been converted to NSR

Dofetilide (Tikosyn) should be reserved for individuals in whom AF/AFL is highly symptomatic because the drug can cause life-threatening ventricular arrhythmias.

Therapy with dofetilide (Tikosyn) for initiation, dose escalation (and, if necessary, reinitiation) must be done according to the product labeling, for a minimum of 3 days in an inpatient setting that provides continuous electrocardiographic (ECG) monitoring in the presence of personnel trained in the management of serious ventricular arrhythmias. Additionally, individuals should not be discharged within 12 hours of electrical or pharmacologic conversion to NSR.

- For information on maintenance therapy with dofetilide (Tikosyn), refer to the Guidelines section of this policy.

Duration of authorization: 12 months

Version Effective Date: 2/2026

Title: Eculizumab (Soliris®) and Related Biosimilars, Ravulizumab-cwvz (Ultomiris®) for intravenous administration

MEDICALLY NECESSARY:

For all requests: drug is prescribed at an FDA approved dose and frequency

PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

ECULIZUMAB (SOLIRIS) AND RELATED BIOSIMILARS
Eculizumab (Soliris) and related biosimilars, the Company's non-preferred products for PNH, are considered medically necessary and, therefore, covered for the treatment of PNH in adult individuals, when all of the following criteria are met, including dosing and frequency:

Initial Criteria

- The coverage will be provided for eculizumab (Soliris) and related biosimilars when one of the following is present:
    - There is a documented contraindication or documented nonresponse to ravulizumab-cwvz (Ultomiris).
    - The individual is currently receiving or has previously received a non-preferred product (e.g., eculizumab [Soliris]). (See COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections below).
- Flow cytometry demonstrates one of the following:
    - At least 10% PNH type III red cells
    - Greater than 50% of glycosylphosphatidylinositol-anchored proteins (GPI-AP)–deficient polymorphonuclear (PM) cells
- The individual is transfusion dependent due to PNH.
- The individual has platelet counts of at least 100,000 per cubic millimeter.
- The individual does not have unresolved *Neisseria meningitidis* infection.
- The individual is vaccinated against *N. meningitidis,* unless risk of delaying eculizumab (Soliris) outweighs the risks of developing meningococcal infection.

Continuation Criteria
Eculizumab (Soliris) and related biosimilars are considered medically necessary and, therefore, covered for continuation therapy, when documentation is provided of positive clinical response (e.g., reduction in hemolysis manifested by stabilization of hemoglobin levels and reduction in transfusions from baseline at initiation).

RAVULIZUMAB-CWVZ (ULTOMIRIS™)
Ravulizumab-cwvz (Ultomiris) is considered medically necessary and, therefore, covered for adult and pediatric individuals 1 month of age or older with PNH when all of the following criteria are met:

Initial Criteria

- The individual has a diagnosis of PNH confirmed by high-sensitivity flow cytometry of red and white blood cells with granulocyte or monocyte clone size of at least 5%.
- The individual has lactate dehydrogenase (LDH) level ≥ 1.5 × upper normal limit (UNL) (adult: 100 to 190 units/L at 37°C) at initiation of the therapy.
- The individual does not have history of bone marrow transplantation.
- The individual does not have unresolved *N. meningitidis* infection.
- The individual is vaccinated against *N. meningitidis,* unless risk of delaying ravulizumab-cwvz (Ultomiris) outweighs the risks of developing meningococcal infection.

Continuation Criteria (After 26 Weeks of Therapy)

Ravulizumab-cwvz (Ultomiris) is considered medically necessary and, therefore, covered for continuation therapy following at least 26 weeks of therapy for the treatment of PNH, when documentation is provided of positive clinical response (e.g., reduction in hemolysis manifested by a stabilization of hemoglobin levels and reduction in transfusions from baseline at initiation).

ATYPICAL HEMOLYTIC–UREMIC SYNDROME (aHUS)

ECULIZUMAB (SOLIRIS) AND RELATED BIOSIMILARS

Eculizumab (Soliris) and related biosimilars, the Company's non-preferred products for aHUS, are considered medically necessary and, therefore, covered for the treatment of pediatric and adult individuals with aHUS, when all of the following criteria are met:

Initial Criteria

- The coverage will be provided for eculizumab (Soliris) and related biosimilars, when one of the following is present:
    - There is a documented contraindication or documented nonresponse to ravulizumab-cwvz (Ultomiris)
    - The individual is currently receiving or has previously received a non-preferred product (e.g., eculizumab [Soliris]). (See COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections below).
- Diagnosis of thrombocytopenic purpura (TTP) has been excluded (e.g., normal ADAMTS-13 activity, or ADAMTS-13 activity <5%) OR a trial of plasma exchange did not result in clinical improvement.
- The individual does not have unresolved *N. meningitidis* infection.
- The individual is vaccinated against *N. meningitidis,* unless risk of delaying eclizumab (Soliris) outweighs risks of developing meningococcal infection.
- The individual has an absence of Shiga toxin–producing *Escherichia coli* infection.

Continuation Criteria (After 26 Weeks of Therapy)

Eculizumab (Soliris) and related biosimilars are considered medically necessary and, therefore, covered for continuation therapy following at least 26 weeks of therapy for the treatment of aHUS when documentation is provided of reduction in signs of complement-mediated thrombotic microangiopathy (TMA), including at least two of the following:

- Platelet count increase from baseline at initiation
- Hematologic normalization (maintenance of normal platelet counts and LDH levels for at least 4 weeks)

- Complete complement-mediated TMA response (hematologic normalization plus at least 25% reduction in serum creatinine from baseline for at least 4 weeks)
- TMA-event free status (absence for at least 12 weeks of a decrease in platelet count of greater than 25% from baseline, treatment with plasma exchange or plasma infusion, or new dialysis treatment)
- Reduction in the daily TMA intervention rate (defined as the number of plasma exchange or plasma infusion interventions and the number of new dialysis required per individual per day)

RAVULIZUMAB-CWVZ (ULTOMIRIS)
Ravulizumab-cwvz (Ultomiris) is considered medically necessary and, therefore, covered for adult and pediatric individuals 1 month of age and older with aHUS to inhibit complement-mediated TMA when all of the following criteria are met:

Initial Criteria

- The individual has evidence of TMA, including low platelet count, hemolysis (breaking of red blood cells inside of blood vessels), and decreased kidney function.
- The individual does not have ADAMTS-13 activity <5%.
- The individual does not have unresolved *N. meningitidis* infection.
- The individual is vaccinated against *N. meningitidis* unless risk of delaying ravulizumab-cwvz (Ultomiris) outweighs risks of developing meningococcal infection.
- The individual has an absence of Shiga toxin–producing *E. coli* infection.
- The individual does not have positive direct Coombs test.

Continuation Criteria (After 26 Weeks of Therapy)
Ravulizumab-cwvz (Ultomiris) is considered medically necessary and, therefore, covered for continuation therapy, following treatment of aHUS for at least 26 weeks when there is documentation demonstrating a positive clinical response from baseline (e.g., reduction of plasma exchanges, reduction of dialysis, increased platelet count, reduction of hemolysis).

GENERALIZED MYASTHENIA GRAVIS (gMG)

ECULIZUMAB (SOLIRIS) AND RELATED BIOSIMILARS
Eculizumab (Soliris) and related biosimilars, the Company's non-preferred products for generalized myasthenia gravis (gMG), are considered medically necessary and, therefore, covered for the treatment of adult and pediatric patients six years of age and older with gMG, when all of the following criteria are met:

Initial Criteria

- The coverage will be provided for eculizumab (Soliris) and related biosimilars when one of the following is present:
    - There is a documented contraindication or documented nonresponse to ravulizumab-cwvz (Ultomiris).
    - The individual is currently receiving or has previously received a non-preferred product (e.g., eculizumab [Soliris]). (See COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections below).
- The individual is positive for antiacetylcholine receptor (AchR) antibodies and one of the following:
    -
    - History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation, or
    - History of positive anticholinesterase test, e.g., edrophonium chloride test, or
    - The individual has demonstrated improvement in myasthenia gravis (MG) signs on oral cholinesterase inhibitors, as assessed by the treating professional provider.
- The individual meets Myasthenia Gravis Foundation of America (MGFA) Clinical Classification* Class II to IV.
- The individual has a Myasthenia Gravis–Specific Activities of Daily Living scale (MG-ADL)** total score of six or greater.
- Documentation of prior treatments with one of the following regimens:
    - Two or more immunosuppressive agents (azathioprine [AZA], cyclophosphamide [CY], cyclosporine [CYC], mycophenolate mofetil [MFF], methotrexate [MTX], or tacrolimus [TAC]) without symptom control, or
    - One immunosuppressive therapy and chronic intravenous immunoglobulin or plasma exchange for 12 months without symptom control
- The individual does not have unresolved *N. meningitidis* infection.
- The individual is vaccinated against *N. meningitidis,* unless risk of delaying eclizumab (Soliris) outweighs risks of developing meningococcal infection.

Continuation Criteria (After 26 Weeks of Therapy)
Eculizumab (Soliris) and related biosimilars are considered medically necessary and, therefore, covered for continuation therapy following at least 26 weeks of therapy for the treatment of gMG when documentation is provided of positive clinical response (e.g., demonstration of a clinically meaningful response regarding daily activities [≥3 point improvement in the MG-ADL from baseline]).

RAVULIZUMAB-CWVZ (ULTOMIRIS)
Ravulizumab-cwvz (Ultomiris) is considered medically necessary and, therefore, covered for the treatment of adult individuals with gMG when all of the following criteria are met:

Initial Criteria

- The individual is positive for AchR antibodies and one of the following:
    - History of abnormal neuromuscular transmission test demonstrated by SFEMG or repetitive nerve stimulation, or
    - History of positive anticholinesterase test, e.g., edrophonium chloride test, or
    - The individual has demonstrated improvement in MG signs on oral cholinesterase inhibitors, as assessed by the treating professional provider.
- The individual meets MGFA Clinical Classification* Class II to IV.
- The individual has a MG-ADL** total score of six or greater.
- Documentation of prior treatments with one of the following regimens:
    - Azathioprine: must have been on AZA for ≥6 months (180 days) and have been on a stable dose for ≥2 months (60 days)
    - Immunosuppressive therapies (i.e., MMF, MTX, CYC, TAC, or CY), must have been on the immunosuppressive therapy for ≥3 months (90 days) and have been on a stable dose for ≥ 1 month (30 days)
    - Oral corticosteroids, must have been on a stable dose for ≥4 weeks (28 days)
    - A cholinesterase inhibitor, at the time of the screening visit, must have been on a stable dose for ≥2 weeks (14 days)
- The individual does not have unresolved *N. meningitidis* infection.
- The individual is vaccinated against *N. meningitidis,* within 3 years, or individuals who initiate ravulizumab-cwvz (Ultomiris) treatment less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination

Continuation Criteria (After 26 Weeks of Therapy)
Ravulizumab-cwvz (Ultomiris) is considered medically necessary and, therefore, covered for continuation therapy following at least 26 weeks of therapy for the treatment of gMG when documentation is provided of positive clinical response (e.g., demonstration of a clinically meaningful response regarding daily activities [≥3 point improvement in the MG-ADL from baseline]).

NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD)

ECULIZUMAB (SOLIRIS) AND RELATED BIOSIMILARS
Eculizumab (Soliris) and related biosimilars, the Company's non-preferred products for NMOSD, are considered medically necessary and, therefore, covered for the treatment

of pediatric and adult individuals with NMOSD, when all of the following criteria are met:

Initial Criteria

- The coverage will be provided for eculizumab (Soliris) and related biosimilars when one of the following is present:
    - There is a documented contraindication or documented nonresponse to ravulizumab-cwvz (Ultomiris).
    - The individual is currently receiving or has previously received a non-preferred product (e.g., eculizumab [Soliris]). (See COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections below).
- The individual has diagnosis of neuromyelitis optica NMOSD.
- The individual is anti-aquaporin-4 (AQP4) antibody seropositive.
- The individual had historical relapse of at least two relapses in the last 12 months or three relapses in the last 24 months, with at least one relapse in the 12 months prior to the initiation of the therapy.
- The individual does not have unresolved *N. meningitidis* infection.
- The individual is vaccinated against *N. meningitidis*, unless risk of delaying eclizumab (Soliris) outweighs the risks of developing meningococcal infection.

Continuation Criteria

Eculizumab or related biosimilars are considered medically necessary for continued use in adult individuals with diagnosis of NMOSD when the initial criteria are met AND there is documentation of a positive clinical response (e.g., reductions in relapse or reduction in new onset of symptoms).

RAVULIZUMAB-CWVZ (ULTOMIRIS)

Ravulizumab-cwvz (Ultomiris) is considered medically necessary and, therefore, covered for the treatment of adult individuals with NMOSD when all of the following criteria are met:

Initial Criteria

- The individual has diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
- The individual is anti-aquaporin-4 (AQP4) antibody seropositive.
- The individual had at least one attack or relapse in the last 12 months prior to initiation of the therapy.
- The individual has Expanded Disability Status Scale score ≤7.
- The individual has body weight ≥40 kilograms.
- The individual does not have unresolved N. meningitidis infection.
- The individual is vaccinated against N. meningitidis, unless risk of delaying eclizumab (Soliris) outweighs the risks of developing meningococcal infection.

Continuation Criteria

Ravulizumab-cwvz (Ultomiris) is considered medically necessary for continued use in adult individuals with diagnosis of NMOSD when the initial criteria are met AND there is documentation of a positive clinical response (e.g., reductions in relapse or reduction in new onset of symptoms).

COMPANY-DESIGNATED PREFERRED PRODUCTS FOR PAROXYSMAL NOCTURNAL

HEMOGLOBINURIA, ATYPICAL HEMOLYTIC–UREMIC SYNDROME, GENERALIZED MYASTHENIA GRAVIS AND NEUROMYELITIS OPTICA SPECTRUM DISORDER

Although there are additional brand(s) of terminal complement inhibitor therapy on the market for the treatment of PNH, aHUS, gMG, and NMOSD there is no reliable evidence of the superiority of any one brand compared with other brand(s). The Company has designated ravulizumab-cwvz (Ultomiris) as its preferred product.

This product is less costly and at least as likely to produce equivalent therapeutic results as the non-preferred products, which include, but are not limited to, eculizumab (Soliris) or related biosimilars.

For individuals who meet the above medical necessity criteria, use of the Company-designated preferred product, ravulizumab-cwvz (Ultomiris), is considered medically necessary and, therefore, covered.

NON-PREFERRED PRODUCTS FOR PAROXYSMAL NOCTURNAL HEMOGLOBINURIA, ATYPICAL HEMOLYTIC–UREMIC SYNDROME, GENERALIZED MYASTHENIA GRAVIS AND NEUROMYELITIS OPTICA SPECTRUM DISORDER

For individuals who meet the above medical necessity criteria, use of non-preferred products (which include, but are not limited to, eculizumab [Soliris]) or related biosimilars is considered medically necessary and, therefore, covered in at least one of the following instances*:

- Individual has a documented contraindication or documented non-response to the preferred product ravulizumab-cwvz (Ultomiris).
- Individual is currently receiving or has previously received a non-preferred product.

*Requests for the use of non-preferred products that do not meet either of these conditions are considered not medically necessary and, therefore, not covered.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Efbemalenograstim alfa-vuxw (Ryzneuta®), Eflapegrastim-xnst (Rolvedon™), Pegfilgrastim (Neulasta®) and Related Biosimilars

MEDICALLY NECESSARY:

COMPANY-DESIGNATED PREFERRED PRODUCTS
Although there are many pegfilgrastim products on the market, there is no reliable evidence of the superiority of any of these products. The preferred products, pegfilgrastim (Neulasta) and pegfilgrastim-apgf (Nyvepria), are less costly and at least as likely to produce equivalent therapeutic results as the nonpreferred products.*

PREFERRED PEGFILGRASTIM PRODUCTS	**NONPREFERRED PRODUCTS***
Pegfilgrastim (Neulasta)	pegfilgrastim-bmez [Ziextenzo]
Pegfilgrastim-apgf (Nyvepria)	pegfilgrastim-cbqv [Udenyca]
	pegfilgrastim-jmdb [Fulphila]
	pegfilgrastim-pbbk [Fylnetra]
	pegfilgrastim-fpgk [Stimufend]
	eflapegrastim-xnst [Rolvedon]
	efbemalenograstim alfa-vuxw [Ryzneuta]

According to the US Food and Drug Administration (FDA), "a biosimilar is a biological product that has no clinically meaningful differences from the existing FDA-approved reference product. All biosimilar products meet the FDA's rigorous standards for approval for the indications described in the product labeling. Once a biosimilar has been approved by the FDA, the safety and effectiveness of these products have been established, just as they have been for the reference product." Coverage of a biosimilar product as an alternate to a reference product is not considered a form of step therapy by the Company.

NONPREFERRED PRODUCTS*
Use of the nonpreferred pegfilgrastim/eflapegrastim/efbemalenograstim products is considered medically necessary and, therefore, covered only for individuals who are currently receiving or have previously received a nonpreferred product for the specified pegfilgrastim indication.

If the individual has not previously received a nonpreferred pegfilgrastim biosimilar, efbemalenograstim or eflapegrastim product to treat the specified indication, these nonpreferred products are only eligible for coverage when the individual has contraindication(s) or intolerance(s) to the Company-designated preferred products.

EFBEMALENOGRASTIM ALFA-VUXW (RYZNEUTA), EFLAPEGRASTIM-XNST (ROLVEDON), PEGFILGRASTIM (NEULASTA), AND RELATED BIOSIMILARS
Efbemalenograstim alfa-vuxw (Ryzneuta), eflapegrastim-xnst (Rolvedon), pegfilgrastim (Neulasta), and related biosimilars are considered medically necessary and, therefore, covered when used as recommended by the then-current National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) guidelines for any of the following indications:

- Prophylaxis of myelosuppressive chemotherapy-induced febrile neutropenia or other dose-limiting neutropenic events in high-risk[†] (>20% overall risk of febrile neutropenia) individuals with solid tumors and nonmyeloid malignancies receiving treatment in the curative/adjuvant or palliative settings
- Prophylaxis of myelosuppressive chemotherapy-induced febrile neutropenia or other dose-limiting neutropenic events in intermediate-risk***** (10%–20% overall risk of febrile neutropenia with one of more risk factors below) or low-risk[†] (<10% overall risk of febrile neutropenia with two or more risk factors below) in individuals with solid tumors and nonmyeloid malignancies receiving treatment in the curative/adjuvant or palliative settings who have one or more of the following risk factors:
    - Prior chemotherapy or radiation therapy
    - Persistent neutropenia
    - Bone marrow involvement by tumor
    - Recent surgery and/or open wounds
    - Liver dysfunction (bilirubin >2 mg/dL)
    - Renal dysfunction (creatinine clearance <50 mL/min)
    - Age greater than 65 years receiving full chemotherapy dose intensity
    - Poor performance status (Eastern Cooperative Oncology Group [ECOG] Performance Status 3–4)
    - Human immunodeficiency virus (HIV) infection with low CD4 counts (450 cells/mm^3 or less)
    - Chronic immunosuppression in the posttransplant setting, including organ transplant

*[†]*See Attachment A for examples of disease settings and chemotherapy regimens with a high (>20%) or intermediate (10%–20%) risk for febrile neutropenia* ***(Note: These are not all-inclusive lists.)***

- Prophylaxis of chemotherapy-induced febrile neutropenia in individuals with one of the following indications, regardless of risk status:
    - Acute lymphoblastic leukemia (ALL) or acute myeloid leukemia (AML) in pediatric individuals who have relapsed disease and have serious/life-threatening neutropenic infection
    - Diffuse aggressive lymphoma in individuals age 65 years and older treated with the curative chemotherapy regimen cyclophosphamide, doxorubicin, vincristine, prednisone, and rituximab (R-CHOP)
    - In pediatric individuals in whom dose-intense chemotherapy is administered for an indication that is known to have a survival benefit (e.g., Ewing sarcoma)
    - Dose-dense therapy (standard doses given more frequently) for the adjuvant treatment of high-risk breast cancer or for use of high-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-MVAC) in urothelial cancer

- Prophylaxis of chemotherapy-induced febrile neutropenia in individuals with Wilms tumor (nephroblastoma), when administered with Regimen M and Regimen I for courses of either:
    - Cyclophosphamide and etoposide
    - Cyclophosphamide, doxorubicin, and vincristine

- Secondary prophylaxis in individuals who have experienced a neutropenic event from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose or treatment delay may compromise disease-free or overall survival or treatment outcome
- Therapeutic use in individuals with cancer who have fever and neutropenia and are at high risk for infection-associated complications or who have prognostic factors that are predictive of poor clinical outcomes. High-risk features include the following factors:
    - Expected prolonged (>10 days) and profound ($<0.1 \times 10^9$/L) neutropenia
    - Age greater than 65 years
    - Pneumonia

    - Hypotension and multiorgan dysfunction (sepsis syndrome)
    - Invasive fungal infection
    - Hospitalization at the time of fever development
    - Other clinically documented infections
    - Prior episode of febrile neutropenia

- Hematopoietic subsyndrome of acute radiation syndrome (H-ARS): Therapeutic use after accidental or intentional total body radiation of myelosuppressive doses (>2 Gy), if prolonged delays secondary to neutropenia are expected.
    - Use of the on-body injector for Neulasta (Neulasta Onpro kit) has not been studied and is not recommended for this indication.
- Mobilization of peripheral blood progenitor cells prior to autologous transplantation in individuals with hematological malignancies, when used alone, after chemotherapy, or in combination with plerixafor**.**
- After autologous or allogeneic hematopoietic stem cell transplant to reduce the duration of severe neutropenia.

Duration of authorization: 12 months Version

Effective Date: 05/2026

Title: Efgartigimod alfa - fcab (Vyvgart) and efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)

MEDICALLY NECESSARY:

EFGARTIGIMOD ALFA-FCAB (VYVGART) AND EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC (VYVGART HYTRULO)

Generalized myasthenia gravis (gMG)
Efgartigimod alfa-fcab (Vyvgart) and efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) are considered medically necessary and, therefore, covered for the treatment of adult individuals with generalized gMG when all of the following criteria are met:

- The individual is anti-acetylcholine receptor (AChR) antibody-positive.
- The individual meets Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV.
- The individual has a Myasthenia Gravis–Specific Activities of Daily Living scale (MG-ADL) total score of five or greater.
- The individual is on a stable dose of MG therapy either in combination or alone of any of the following medication:
    - Acetylcholinesterase (AChE) inhibitors
    - Steroids
    - Nonsteroidal immunosuppressive therapies (NSISTs)

EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC (VYVGART HYTRULO)

Chronic inflammatory demyelinating polyneuropathy (CIDP)
Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) is considered medically necessary and, therefore, covered for the treatment of adult individuals with CIDP when all of the following criteria are met:

- The individual is 18 years of age or older
- The individual has a diagnosis of CIDP when all of the following criteria are met:
    - The individual has progressive or relapsing motor or sensory impairment caused by neuropathy in more than one limb for at least 2 months
    - The individual has at least one of the following electrodiagnostic findings of demyelination:
        - Motor distal latency prolongation in two nerves
        - Reduction of motor conduction velocity in two nerves
        - Prolongation of F-wave latency in two nerves
        - Absence of F-waves in at least one nerve
        - Motor conduction block in at least one nerve
        - Abnormal temporal dispersion in at least two nerves
        - Distal compound muscle action potential (CMAP) duration increase in at least one nerve
- The individual is being treated by or under the supervision of a neurologist

- The individual has had previous treatment with, or has contraindication or intolerance to, an intravenous immune globulin (IVIG) or subcutaneous immune globulin (SCIG) product

Duration of authorization: 12 months

Version Effective Date: 10/07/2024

Title: Eladocagene exuparvovec-tneq (Kebilidi™)

MEDICALLY NECESSARY:

Eladocagene exuparvovec-tneq (Kebilidi™) is considered medically necessary, and, therefore, covered when ALL of the following criteria are met in individuals with aromatic L-amino acid decarboxylase (AADC) deficiency:

- Adults and pediatric individuals who have achieved skull maturity assessed by neuroimaging
- Prescribed by or in consultation with a pediatric neurologist or a neurologist for adults
- Individual's diagnosis is confirmed based on ALL of the following:
    - Genetic testing showing biallelic pathogenic variation(s) in the DOPA decarboxylase (DDC) gene
    - Reduced levels of 5-hydroxyindoleacetic acid (5-HIAA), homovanillic acid (HVA) and 3 methoxy-4-hydroxyphenylglycol (MHPG) and high concentrations of 3-O-methyldopa (3-OMD), L-Dopa, and 5-OH tryptophan (5-HTP) in the cerebral spinal fluid (CSF)
    - Reduced aromatic L-amino acid decarboxylase (AADC) activity in the plasma
- Individual presents with classic clinical characteristics of AADC deficiency, such as oculogyric crises, hypotonia, and developmental delay
- Individual does not have any significant structural brain abnormality
- Individual experiences persistent neurological defects despite standard medical therapy (e.g., dopamine agonists, monoamine oxidase inhibitor, pyridoxine or other forms of vitamin B6)
- Individual does not have an anti-AAV2 neutralizing antibody titer over 1200 folds
- Individual does not have pyridoxine 5'-phosphate oxidase or tetrahydrobiopterin (BH4) deficiency
- Individual has not received prior gene therapy treatment

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Elivaldogene Autotemcel [eli-cel (Skysona®)]

MEDICALLY NECESSARY:

Elivaldogene autotemcel (Skysona®) is considered medically necessary and, therefore, covered for the treatment of cerebral adrenoleukodystrophy (CALD) when the individual meets ALL of the following criteria:

- Male, age 4 years to 17 years
- Documentation of adrenoleukodystrophy as demonstrated by meeting BOTH of the following:
    - Genetic confirmation of a pathogenic variant, or likely pathogenic variant, in the adenosine triphosphate binding cassette, sub family D member 1 (ABCD1) gene
    - Elevated very-long-chain fatty acid levels according to the standard reference values of the performing laboratory
- Documentation of early, active CALD as demonstrated by meeting ALL of the following:
    - Neurologic function score (NFS) less than or equal to 1
    - Gadolinium enhancement (GdE+) on brain magnetic resonance imaging (MRI)
    - Loes score between 0.5 and 9
- Has not received a prior allogeneic hematopoietic stem cell transplant (allo-HSCT)
- Documentation of ALL of the following:
    - Adequate hepatic function by meeting ALL of the following:
        - Aspartate aminotransferase values are no greater than 2.5 times the upper limit of normal
        - Alanine aminotransferase values are no greater than 2.5 times the upper limit of normal
        - Total bilirubin values are no greater than 3.0 mg/dL
    - Adequate hematological function as evidenced by ALL of the following:
        - Peripheral blood absolute neutrophil count of at least 1,500 cells/mm^3
        - Platelet count of at least 100,000 cells/mm^3
        - Hemoglobin of at least 10 g/dL
        - No uncorrected bleeding disorder
    - Adequate renal function by meeting ONE of the following:
        - Estimated creatinine clearance is at least 50 mL/min
        - Estimated glomerular filtration rate is at least 70 mL/minute/1.73 m^2
    - Adequate cardiac function as evidenced by a left ventricular ejection fraction greater than 40%
    - Prior to collection of cells for manufacturing, screening for ALL of the following is negative:
        - Hepatitis B virus
        - Hepatitis C virus
        - Human T-lymphotropic virus 1 and 2
        - Human immunodeficiency virus 1 and 2
- Gene replacement therapy is prescribed by a hematologist, a neurologist, and/or a stem cell transplant specialist, who attest(s) to the following:

- No active bacterial, viral, fungal or parasitic infection
- No prior or current malignancy or myeloproliferative disorder
- No familial cancer syndrome or a history of such in their immediate family
- The individual would otherwise have been eligible to receive HSCT, but is unable to receive due to not having a matched sibling donor (10/10 HLA match [excluding female heterozygotes])

Duration of authorization: 12 months

Version Effective Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Enzyme Replacement Therapy for Acid Sphingomyelinase Deficiency (ASMD)**
Drugs	Xenpozyme (olipudase alfa-rpcp)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist experienced in the treatment of ASMD
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	• Medication is prescribed at an FDA approved dose
	• Member has a diagnosis of ASMD confirmed by one of the following:
	  o Deficiency in acid sphingomyelinase (ASM) enzyme activity (as measured by peripheral blood leukocytes, cultured skin fibroblasts, or dried blood spots)
	  o Sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation
	• Member has a clinical presentation consistent with ASMD type B or type A/B
	• Documentation of members height and weight
	• Documentation of baseline ALT and AST within 1 month prior to initiation of treatment
	
	Re-Authorization:
	• Documentation or provider attestation of positive clinical response (i.e. improvement in splenomegaly, hepatomegaly, pulmonary function, etc.)
	• Medication is prescribed at an FDA approved dose

Review/Revision Date: 2/2026	**If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Title: Eptinezumab-jjmr (VYEPTI™)

MEDICALLY NECESSARY:

Eptinezumab-jjmr (VYEPTI™) is considered medically necessary and, therefore, covered for the preventive treatment of migraine in adult individuals when all of the following criteria are met:

INITIAL CRITERIA

- A neurologist, headache specialist, or pain specialist has established a diagnosis of episodic (4 to 14 headache days per month) or chronic (15 or more headache days per month) migraine
- The individual is 18 years of age or older
- The individual had inadequate response or inability to tolerate a 4-week trial of TWO of the following prophylactic medications:
    - Topiramate
    - Divalproex sodium/valproic acid
    - Beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol
    - Tricyclic antidepressants: amitriptyline, nortriptyline
    - Serotonin-norepinephrine reuptake inhibitor (SNRI) antidepressants: venlafaxine, duloxetine
    - Onabotulinumtoxin-A (Botox) for chronic migraines
- Medication will not be used in combination with another calcitonin gene-related peptide (CGRP) inhibitor (e.g., for episodic or chronic migraines: erenumab [Aimovig], fremanezumab [Ajovy], or galcanezumab [Emgality]; or oral CGRP antagonist for episodic migraines: rimegepant [Nurtec ODT] or atogepant [Qulipta])

CONTINUATION CRITERIA

Documentation of response to therapy as defined by 50 percent reduction in migraine days per month from baseline (defined as at least 4 hours' duration and moderate intensity).

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Enzyme Replacement Therapy for Adenosine Deaminase Severe Combined Immune Deficiency (e.g., elapegademase-lvlr [Revcovi])

MEDICALLY NECESSARY:

Elapegademase-lvlr (Revcovi™) is considered medically necessary and, therefore, covered for the treatment of individuals with adenosine deaminase deficiency with severe combined immunodeficiency (ADA-SCID), when all of the following criteria, including Dosing and Frequency Requirements, are met:

- Diagnosis of adenosine deaminase deficiency (ADA) is confirmed by one of the following:
    - Molecular genetic testing that reveals biallelic pathogenic variation(s) of the ADA gene
    - Deficiency or absence of ADA catalytic activity (<1% of normal) in hemolysates (in untransfused individuals) or in extracts of dried blood spots or other cells (e.g., blood mononuclear cells, fibroblasts)
    - An increase above laboratory standard (0.2 ± 0.1 pmol/10^6 cells) in deoxyadenosine triphosphate (dATP) levels in erythrocytes
- Individual is not a candidate for, or has failed, bone marrow transplantation
- Absence of severe thrombocytopenia
- Dosing and Frequency: Administered as an intramuscular injection. The starting weekly dose is 0.4 mg/kg based on ideal body weight or actual weight whichever is greater, divided into two doses (0.2 mg/kg twice a week), for a minimum of 12 to 24 weeks until immune reconstitution is achieved. After that, the dose may be gradually adjusted down to maintain trough ADA activity over 30 mmol/hr/L, trough deoxyadenosine nucleotides (dAXP) level under 0.02 mmol/L, and/or to maintain adequate immune reconstitution based on clinical assessment of the individual. Further monitoring of levels is required with the possibility of further dosage adjustment.

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: Enzyme Replacement Therapy for Mucopolysaccharidosis (e.g., Aldurazyme®, Elaprase®, Vimizim®, Naglazyme®, Mepsevii™, etc.)

MEDICALLY NECESSARY:

Laronidase (Aldurazyme®) is considered medically necessary and, therefore, covered for use in individuals aged 6 months or older, when all of the following criteria are met, including dosing and frequency:

- Diagnosis of Hurler or Hurler-Scheie forms of mucopolysaccharidosis I (MPS I) or Scheie form of MPS I with moderate-to-severe symptoms, confirmed by one of the following:
    - Demonstrated deficiency of the lysosomal alpha-L-iduronidase (e.g., in peripheral blood leukocytes, plasma, or cultured fibroblasts)
    - Confirmation of biallelic pathogenic variant(s)in the IDUA gene
- Dosing and frequency: 0.58 mg/kg of body weight administered once weekly as an intravenous infusion

Idursulfase (Elaprase®) is considered medically necessary and, therefore, covered for use for individuals aged at least 16 months when all of the following criteria are met, including dosing and frequency:

- Diagnosis of Hunter syndrome (MPS II) confirmed by one of the following:
    - Deficiency of iduronidate 2-sulfatase in leukocytes, fibroblasts, or plasma, and documentation of normal enzymatic activity of at least one other sulfatase in the same tissue type
    - Confirmation of a hemizygous pathogenic variant(s) in the IDS gene
- Dosing and frequency: 0.5 mg/kg of body weight administered once weekly as an intravenous infusion

Elosulfase alfa (Vimizim®) is considered medically necessary and, therefore, covered for use in individuals aged at least 5 years, when all of the following criteria are met, including dosing and frequency:

- Diagnosis of MPS Type IVA (MPS IVA), also called Morquio A syndrome, has been confirmed by one of the following:
    - Deficiency of N-acetylgalactosamine-6-sulphatase (GALNS) in cultured fibroblasts or leukocytes
    - Confirmation of biallelic pathogenic variant(s) in the GALNS gene
- Dosing and frequency: 2 mg/kg given intravenously once every week

Galsulfase (Naglazyme®) is considered medically necessary and, therefore, covered for use in individuals aged at least 5 years when all of the following criteria are met, including dosing and frequency:

- Diagnosis of MPS type VI (MPS VI, Maroteaux-Lamy syndrome) has been confirmed by one of the following:
    - Deficiency of N-acetylgalactosamine 4-sulfatase [ARSB] in leukocytes, fibroblasts, and dried blood spots

    - Confirmation of biallelic pathogenic variant(s) in the ARSB gene
- Dosing and frequency: 1 mg/kg of body weight, administered once weekly as an intravenous infusion

Vestronidase alfa-vjbk (Mepsevii™) is considered medically necessary and, therefore, covered for use in infants aged at least 5 months, children, and adult individuals when all of the following criteria are met, including dosing and frequency:

- Diagnosis of MPS type VII (MPS VII, Sly syndrome) has been confirmed by one of the following:
    - Deficiency of beta-glucuronidase in peripheral blood leukocytes or cultured fibroblasts
    - Genetic testing confirming pathogenic variant(s) in the GUSB gene
- Dosing and frequency: 4 mg/kg administered by intravenous infusion every 2 weeks

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: Erythropoiesis-Stimulating Agents (ESAs)

MEDICALLY NECESSARY:

ANEMIA ASSOCIATED WITH CANCER AND RELATED ONCOLOGIC CONDITIONS
MEDICALLY NECESSARY CRITERIA FOR EPOETIN ALFA (EPOGEN®, PROCRIT®), DARBEPOETIN ALFA (ARANESP®) AND RELATED BIOSIMILARS (e.g., EPOETIN ALFA-EPBX [RETACRIT™])

Initiation Criteria for Erythropoiesis-Stimulating Agents (ESAs) Therapy for Cancer and Related Oncologic Conditions
Erythropoiesis-stimulating agents such as epoetin alfa (Epogen®, Procrit®), darbepoetin alfa (Aranesp®), or related biosimilars (e.g., epoetin alfa-epbx [Retacrit™]) are considered medically necessary and, therefore, covered when any of the following criteria are met:

- The individual has anemia secondary to a regimen of myelosuppressive anticancer chemotherapy for non-myeloid malignancies and has no other identifiable cause of anemia, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
    - The hemoglobin (Hb) level immediately prior to the first administration of ESA is less than 10 g/dL (or hematocrit [HCT] is less than 30 percent).
- The individual is undergoing palliative treatment.

Treatment of Chemotherapy-Induced Anemia

- As treatment of symptomatic chemotherapy-Induced anemia in individuals with cancer with any of the following:
    - Have moderate to severe chronic kidney disease
    - Are undergoing palliative treatment
    - Are receiving myelosuppressive chemotherapy and have no other identifiable cause of anemia
    - Refuse blood transfusions in select cases

National Comprehensive Cancer Network (NCCN) note: Erythropoiesis-stimulating agents are not recommended when myelosuppressive chemotherapy is given with curative intent (except for individuals who refuse blood transfusions), for individuals with cancer who are not receiving therapy, or for individuals receiving non-myelosuppressive therapy

Myelodysplastic Syndrome
For individuals with symptomatic anemia related to myelodysplastic syndrome, as treatment of lower risk† disease, when all of the following criteria are met:

- Individuals with one of the following:
    - As an alternative to lenalidomide, for individuals, with del(5q), with or without one other cytogenetic abnormality (except those involving chromosome 7) and serum erythropoietin ≤500 mU/mL

    - For individuals with no del(5q), with or without one other cytogenetic abnormalities ring sideroblasts <15 percent (or ring sideroblasts <5% with an SF3B1 mutation) with serum erythropoietin ≤500 mU/mL
        - As a single agent (NCCN preferred regimen)
        - In combination with lenalidomide or a granulocyte-colony stimulating factor (G-CSF) following no response (despite adequate iron stores) to an erythropoiesis-stimulating agent (ESA) alone or luspatercept-aamt
    - For individuals with no del(5q), with or without one other cytogenetic abnormalities ring sideroblasts ≥15 percent (or ring sideroblasts ≥5% with an SF3B1 mutation), with serum erythropoietin ≤500 mU/mL following no response to luspatercept-aamt
        - As a single agent
        - In combination with a granulocyte-colony stimulating factor (G-CSF)
- Hb is less than 10 g/dL (or HCT is less than 30 percent) at the initiation of therapy.
- The intent of therapy is to maintain a Hb/HCT level no greater than 10-12 g/dL (Hb) or 30-36 percent (HCT).

†Lower risk defined as IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate).
There are three main prognostic scoring systems. See Guidelines Section for more details.

Myelofibrosis
For individuals with anemia related to myelofibrosis when all both of the following criteria are met:

- Endogenous serum erythropoietin level less than 500mU/mL
- Hb is less than 10 g/dL (or HCT is less than 30 percent) at the initiation of therapy and one of the following:
    - With presence of symptomatic splenomegaly and/or constitutional symptoms currently controlled on a JAK inhibitor, to be given in combination with ruxolitinib
    - With no symptomatic splenomegaly and/or constitutional symptoms

Continuation of ESA Therapy for Cancer and Related Oncologic Conditions
Professional providers should use the lowest dose of ESA required to avoid red blood cell (RBC) transfusions. ESA treatment is considered medically necessary and, therefore, covered for eight weeks after the final dose of a myelosuppressive chemotherapy regimen.

NOT MEDICALLY NECESSARY CRITERIA FOR EPOETIN ALFA (EPOGEN®, PROCRIT®), RELATED BIOSIMILARS (e.g., EPOETIN ALFA-EPBX [RETACRIT™]), AND DARBEPOETIN ALFA (ARANESP®)
An ESA such as epoetin alfa (Epogen®, Procrit®), related biosimilars (e.g., epoetin alfa-epbx [Retacrit™]), or darbepoetin alfa (Aranesp®) is considered not medically necessary and, therefore, not covered for any of the following indications because the available published peer-reviewed literature does not support its use:

- Anemia of cancer not related to cancer treatment
- Prophylactic use to prevent chemotherapy-induced anemia

- Prophylactic use to reduce tumor hypoxia
- Individuals with erythropoietin-type resistance due to neutralizing antibodies
- Anemia in individuals who have cancer or are undergoing cancer treatment, when anemia is due to folate deficiency, vitamin B12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis
- Anemia associated with the treatment of acute or chronic myelogenous leukemia (AML, CML) or erythroid cancers
- Any anemia associated only with radiotherapy
- For individuals receiving non-myelosuppressive therapy
- For individuals with pure red cell aplasia that begins following treatment with epoetin alfa or other erythropoietin protein drugs

ANEMIA ASSOCIATED WITH NON-ONCOLOGIC CONDITIONS

MEDICALLY NECESSARY CRITERIA FOR EPOETIN ALFA (EPOGEN®, PROCRIT®), RELATED BIOSIMILARS (e.g., EPOETIN ALFA-EPBX [RETACRIT™]), AND DARBEPOETIN ALFA (ARANESP®).

Epoetin alfa (Epogen®, Procrit®), related biosimilars (e.g., epoetin alfa-epbx [Retacrit™]), or darbepoetin alfa (Aranesp®) are considered medically necessary and, therefore, covered for the treatment of anemia associated with the following indications when the following criteria for each indication are met:

Acquired Immunodeficiency Syndrome (HIV/AIDS)

For individuals who have HIV/AIDS and anemia when all of the following criteria are met:

- Endogenous serum erythropoietin level of 500mU/mL or less that is induced by treatment with zidovudine (AZT) administered at 4,200 mg/week or less.
- Hb is less than 10g/dL or Hct is less than 30 percent at the initiation of therapy.

Chronic Kidney Disease (CKD)

For individuals who have anemia related to CKD when all of the following criteria are met:

- Hb is less than 10 g/dL (or HCT is less than 30 percent) at the initiation of therapy.
- Glomerular filtration rate (GFR) is less than 60 mL/min/1.73 m^2 for 3 or more months.

MEDICALLY NECESSARY CRITERIA FOR EPOETIN ALFA (EPOGEN®, PROCRIT®) AND RELATED BIOSIMILARS (e.g., EPOETIN ALFA-EPBX [RETACRIT™])

Epoetin alfa (Epogen®, Procrit®) and related biosimilars (e.g., epoetin alfa-epbx [Retacrit™]) are considered medically necessary and, therefore, covered for the treatment of anemia associated with the following indication when the following criteria are met:

Perisurgical Adjuvant Therapy

For individuals with anemia who are undergoing elective, nonvascular, noncardiac, nonvascular surgery, when all of the following criteria are met:

- Hb is between 10-13 g/dL (or HCT is between 30-39 percent).
- The individual is at high risk for perioperative blood loss.
- The individual is not a candidate for autologous blood transfusion.
- The individual is expected to lose two or more units of blood.
- The individual has been evaluated to ensure that anemia is due to chronic disease.

CONTINUATION OF ESA THERAPY WITH EPOETIN ALFA (EPOGEN®, PROCRIT®) AND RELATED BIOSIMILARS (e.g., EPOETIN ALFA-EPBX [RETACRIT™])

During ESA therapy, many individuals eventually require supplemental iron. In order to guide appropriate supplementation, iron stores should be regularly monitored to ensure a transferrin saturation greater than 20 percent and/or serum ferritin levels greater than 100 ng/mL.

MEDICALLY NECESSARY CRITERIA FOR METHOXYPOLYETHYLENE GLYCOL-EPOETIN BETA (MIRCERA®)

Methoxypolyethylene glycol-epoetin beta (Mircera®) is considered medically necessary and, therefore, covered for the treatment of the following indications when the following criteria are met:

- Anemia associated with chronic kidney disease in adults on hemodialysis and adults not on hemodialysis
- Anemia associated with chronic kidney disease in pediatric individuals 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA

CONTINUATION OF ESA THERAPY WITH METHOXYPOLYETHYLENE GLYCOL-EPOETIN BETA (MIRCERA®)

Methoxypolyethylene glycol-epoetin beta (Mircera®) is considered medically necessary and, therefore, covered for continuation of the treatment when the following criteria are met:

- Professional providers use the lowest dose of ESA required to avoid red blood cell (RBC) transfusions. During therapy, evaluation of iron status and correction or exclusion of other causes of anemia is required.
- If Hb does not rise adequately over a 12-week escalation period: Additional dose increase is unlikely to improve response and may increase risk. Evaluate other causes of anemia and discontinue therapy if responsiveness does not improve.

NOT MEDICALLY NECESSARY CRITERIA FOR METHOXYPOLYETHYLENE GLYCOL-EPOETIN BETA (MIRCERA®)

Methoxypolyethylene glycol-epoetin beta (Mircera®) is considered not medically necessary and, therefore, not covered for any of the following indications because the available published peer-reviewed literature does not support its use:

- Treatment of anemia due to cancer chemotherapy or radiation
- Substitute for RBC transfusions in individuals who require immediate correction of anemia

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Etranacogene dezaparvovec-drlb (Hemgenix®)

MEDICALLY NECESSARY:

Etranacogene dezaparvovec-drlb (Hemgenix®) is considered medically necessary and, therefore, covered for the treatment of hemophilia B in individuals 18 years of age and older when they meet ALL of the following criteria:

- Documentation of the diagnosis of moderately severe or severe hemophilia B as evidenced by a baseline (without Factor IX replacement therapy) Factor IX level of less than or equal to 2% of normal.
- ONE of the following:
    - Documentation of BOTH of the following:
        - Receiving routine prophylaxis with Factor IX therapy continuously for at least 2 months
        - According to the prescriber, has at least a 150 exposure-day history of Factor IX therapy
    - Documentation of BOTH of the following:
        - History of life-threatening hemorrhage
        - On-demand use of Factor IX therapy was required for this life-threatening hemorrhage
    - Documentation of BOTH of the following:
        - History of repeated, serious spontaneous bleeding episodes
        - On-demand use of Factor IX therapy was required for these serious spontaneous bleeding episodes
- Documentation of ALL of the following:
    - BOTH of the following:
        - Factor IX inhibitor titer testing performed within 30 days before receiving etranacogene dezaparvovec-drlb (Hemgenix)
        - No current, or history of, Factor IX inhibitors
    - Adequate hepatic function as evidenced by ALL of the following:
        - Alanine aminotransferase is less or equal to 2 times the upper limit of normal
        - Aspartate aminotransferase is less or equal to 2 times the upper limit of normal
        - Total bilirubin levels are less or equal to 2 times the upper limit of normal
        - Alkaline phosphatase levels are less or equal to 2 times the upper limit of normal
        - No evidence of advanced liver impairment and/or advanced fibrosis. For example, liver elastrography (e.g., greater than or equal to 9 kPA) suggestive of or equal to METAVIR stage 3 disease.
    - Adequate renal function as evidenced by BOTH of the following:
        - Estimated creatinine clearance of at least 30 mL/min
        - Creatinine levels are less or equal to 2 times the upper limit of normal

    - Platelet count of at least 50 × 109/L performed within the last 30 days
    - Prior to receiving etranacogene dezaparvovec-drlb (Hemgenix), BOTH of the following:
        - Screening for active hepatitis B and C is negative
        - Is not currently receiving antiviral therapy for a prior hepatitis B virus or C virus exposure
    - If positive for human immunodeficiency virus (HIV), is controlled on antiviral therapy as evidenced by adequate CD4+ counts of at least 200/µL or by a viral load of less than or equal to 200 copies/mL
    - If positive for HIV, is controlled on antiviral therapy as evidenced by adequate CD4+ counts of at least 200/µL or by a viral load of less than or equal to 200 copies/mL
    - Prescriber attestation of no other coagulation disorders, besides hemophilia B
- No prior history of receiving gene therapy
- Prescriber attestation that prophylactic therapy with Factor IX will not be given once adequate Factor IX levels have been achieved. Use of episodic Factor IX therapy is acceptable for the treatment of bleeds and for surgery/procedures if needed as determined by the hemophilia specialist physician.
- Prescriber attestation that, following etranacogene dezaparvovec-drlb (Hemgenix) infusion, ALL of the following will be performed:
    - Liver enzyme testing to monitor for liver enzyme elevations will be done at least weekly for the first 3 months and periodically thereafter
    - Implementing a course of corticosteroids will be considered if there are clinically relevant increases in alanine aminotransferase levels
    - Individual will undergo monitoring for Factor IX activity at least weekly for the first 3 months and periodically thereafter
    - If the individual has preexisting risk factors for hepatocellular carcinoma, they will receive abdominal ultrasound screenings and be monitored at least annually with alpha-fetoprotein elevations in the 5 years following receipt of etranacogene dezaparvovec-drlb (Hemgenix). Risk factors include a patient with prior history of hepatitis B and/or C, non-alcoholic fatty liver disease, chronic alcohol consumption, nonalcoholic steatohepatitis, and advanced age.
- Gene replacement therapy is prescribed by a hemophilia specialist.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Evinacumab-dgnb (Evkeeza®)

MEDICALLY NECESSARY:

INITIAL THERAPY
Evinacumab-dgnb (Evkeeza) is considered medically necessary and, therefore, covered for the treatment of individuals 5 years of age or older with homozygous familial hypercholesterolemia (HoFH) when all of the following criteria, including dosing and frequency, are met:

- Documented diagnosis of HoFH confirmed by **one** of the following:
    - Documentation of the presence of pathogenic variations at two alleles at the low-density lipoprotein receptor (LDL-R), apolipoprotein B (APO-B), proprotein convertase subtilisin-kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein-1 (*LDLRAP1*) gene locus.
    - Untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL **or** treated LDL-C greater than or equal to 300 mg/dL and **one** of the following:
        - Cutaneous or tendinous xanthomas before 10 years of age
        - Documentation of untreated total cholesterol greater than 250 mg/dL in both parents
- Individual currently has elevated LDL-C levels and meets the criteria for each age group:
    - Individuals 10 years of age and older: not at LDL-C goal despite receiving all of the following therapies for at least 12 weeks, unless documented failure, contraindication, or intolerance, and will continue these therapies while on evinacumab-dgnb (Evkeeza):
        - Maximally tolerated moderate- or high-intensity statin therapy (e.g., atorvastatin, rosuvastatin, simvastatin)
        - Ezetimibe (Zetia)
        - PCSK9 inhibitor (e.g., alirocumab [Praluent], evolocumab [Repatha]), unless individual has two LDLR-negative alleles
    - Individuals 5 to less than 10 years of age: not at LDL-C goal (no prior therapies required)
- Dosing and frequency: 15 mg/kg administered by intravenous (IV) infusion once monthly (every 4 weeks)

CONTINUATION THERAPY
Continuation of evinacumab-dgnb (Evkeeza) is considered medically necessary and, therefore, covered when the individual continues to receive other lipid-lowering therapy (unless documented failure, contraindication, or intolerance) and has a documented reduction in LDL-C of at least 30% since initiation of therapy.

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: Filgrastim (Neupogen®) and Related Biosimilars, and tbo-filgrastim (Granix®)

MEDICALLY NECESSARY:

COMPANY-DESIGNATED PREFERRED PRODUCTS
Although there are many filgrastim products on the market (e.g., filgrastim [Neupogen], filgrastim-aafi [Nivestym], filgrastim-sndz [Zarxio], filgrastim-txid (Nypozi), tbo-filgrastim [Granix], filgrastim-ayow [Releuko]), there is no reliable evidence of the superiority of any one product of filgrastim compared to other products. The Company has designated the following filgrastim products as its preferred products:

- Filgrastim-aafi (Nivestym)
- Filgrastim-sndz (Zarxio)

These products are less costly and at least as likely to produce equivalent therapeutic results as the non-preferred products, which include, but are not limited to, filgrastim (Neupogen), tbo-filgrastim (Granix), any other nonpreferred filgrastim biosimilars.

According to the US Food and Drug Administration (FDA), "a biosimilar is a biological product that has no clinically meaningful differences from the existing FDA-approved reference product. All biosimilar products meet the FDA's rigorous standards for approval for the indications described in the product labeling. Once a biosimilar has been approved by the FDA, the safety and effectiveness of these products have been established, just as they have been for the reference product." Coverage of a biosimilar product as an alternate to a reference product is not considered a form of step therapy by the Company.

NON-PREFERRED PRODUCTS
Use of the non-preferred filgrastim products, which include, but are not limited to, filgrastim (Neupogen), tbo-filgrastim (Granix), filgrastim-ayow (Releuko) and any other non-preferred filgrastim biosimilars is considered medically necessary and, therefore, covered only for individuals who are currently receiving or have previously received a non-preferred product for the specified filgrastim indication.

If the individual has not previously received filgrastim (Neupogen), tbo-filgrastim (Granix), or any other non-preferred filgrastim biosimilars to treat the specified indication, these non-preferred products are only eligible for coverage when the individual has contraindication(s) or intolerance(s) to the Company-designated preferred products.

FILGRASTIM (NEUPOGEN) AND RELATED BIOSIMILARS
Filgrastim (Neupogen) and related biosimilars (e.g., filgrastim-aafi [Nivestym], filgrastim-sndz [Zarxio], filgrastim-txid (Nypozi), filgrastim-ayow [Releuko]) are considered medically necessary and, therefore, covered when used as recommended by the then-current National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) guidelines for any of the following indications:

- Prophylaxis of myelosuppressive chemotherapy–induced febrile neutropenia or other dose-limiting neutropenic events in high-risk (>20% overall risk of febrile neutropenia) individuals with solid tumors and nonmyeloid malignancies receiving treatment in the curative/adjuvant or palliative settings
- Prophylaxis of myelosuppressive chemotherapy–induced febrile neutropenia or other dose-limiting neutropenic events in intermediate-risk (10%–20% overall risk of febrile neutropenia) individuals with solid tumors and nonmyeloid malignancies receiving treatment in the curative/adjuvant or palliative settings who have one or more of the following risk factors:
    - Prior chemotherapy or radiation therapy
    - Persistent neutropenia
    - Bone marrow involvement by tumor
    - Recent surgery and/or open wounds
    - Liver dysfunction (bilirubin >2 mg/dL)
    - Renal dysfunction (creatinine clearance <50 mL/min)
    - Age greater than 65 years receiving full chemotherapy dose intensity
    - Poor performance status (Eastern Cooperative Oncology Group [ECOG] Performance Status 3–4)
    - Human immunodeficiency virus (HIV) infection with low CD4 counts (≤450 cells/mm^3 or less)
    - Chronic immunosuppression in the posttransplant setting, including organ transplant
- Prophylaxis of chemotherapy-induced febrile neutropenia in individuals with acute myeloid leukemia (AML) who are receiving induction chemotherapy for any of the following**:**
    - As a component of repeating the initial successful induction regimen if late relapse (≥12 months since induction regimen)
    - For relapsed or refractory disease in combination with cladribine and cytarabine, with or without mitoxantrone or idarubicin
    - For relapsed or refractory disease in combination with fludarabine and cytarabine, with or without idarubicin
- Prophylaxis of chemotherapy-induced febrile neutropenia in individuals with AML who are receiving consolidation chemotherapy for any of the following**:**
    - In combination with fludarabine, cytarabine, and idarubicin with or without gemtuzumab ozogamicin (preferred only if given during induction) for patients with poor-risk AML with and without TP53-mutation or del17p abnormality, therapy-related AML other than core-binding fact acute myeloid leukemia (CBF-AML), antecedent myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML).
- Prophylaxis of chemotherapy-induced febrile neutropenia or other dose-limiting neutropenic events in low-risk (<10% overall risk of febrile neutropenia) individuals with solid tumors and nonmyeloid malignancies receiving treatment in the curative/adjuvant or palliative settings who have two or more individual-related risk factors.
- Treatment of chemotherapy-induced febrile neutropenia

    - In individuals who have been receiving prophylactic filgrastim
    - Consider in individuals who have not received prophylactic granulocyte colony-stimulating factors but who have risk factors for an infection-associated complication
- For hematopoietic cell transplantation for any of the following:
    - In combination with plerixafor
    - In combination with cyclophosphamide with or without plerixafor
    - As a single agent
    - In combination with disease-specific chemotherapy with or without plerixafor
    - In combination with motixafortide (Aphexda) in individuals with multiple myeloma
- Additional therapy for an insufficient collection of stem cells in combination with plerixafor following treatment with filgrastim alone or filgrastim and disease-specific chemotherapy
- Treatment for hematopoietic cell mobilization for allogeneic donors as a single agent
- Treatment for hematopoietic cell mobilization for autologous donors
    - In combination with plerixafor
    - In combination with cyclophosphamide with or without plerixafor
    - As a single agent
    - In combination with disease-specific chemotherapy with or without plerixafor
    - In combination with motixafortide (Aphexda) in individuals with multiple myeloma
- Therapeutic use in acute lymphoblastic leukemia (ALL) in adult individuals with relapsed/refractory (R/R) Philadelphia chromosome–negative B-ALL, T-ALL, and Philadelphia chromosome–positive B-ALL if refractory to tyrosine kinase inhibitors as a component of:
    - FLAG: induction/consolidation (fludarabine, cytarabine, granulocyte colony-stimulating factor)
    - FLAG-IDA: induction/consolidation (fludarabine, cytarabine, granulocyte colony-stimulating factor; with idarubicin)
- ALL or AML in pediatric individuals who have relapsed disease and have serious/life-threatening neutropenic infection
- Prophylaxis of chemotherapy-induced febrile neutropenia in individuals with Wilms tumor (nephroblastoma), when administered with Regimen M and Regimen I for courses of either:
    - Cyclophosphamide and etoposide
    - Cyclophosphamide, doxorubicin, and vincristine
- Diffuse aggressive lymphoma in individuals age 65 years and older treated with curative chemotherapy regimen cyclophosphamide, doxorubicin, vincristine, prednisone, and rituximab (R-CHOP)
- In pediatric individuals where dose-intense chemotherapy is administered for an indication that is known to have a survival benefit (e.g., Ewing sarcoma)

- Dose-dense therapy (standard doses given more frequently) for the adjuvant treatment of high-risk breast cancer or for the use of high-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer
- Secondary prophylaxis in individuals who have experienced a neutropenic event from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose or treatment delay may compromise disease-free or overall survival or treatment outcome
- Therapeutic use in individuals with cancer who have fever and neutropenia and are at high risk for infection-associated complications or who have prognostic factors that are predictive of poor clinical outcomes. High-risk features include the following factors:
    - Expected prolonged (>10 days) and profound ($<0.1 \times 10^9$/L) neutropenia
    - Age greater than 65 years
    - Pneumonia
    - Hypotension and multiorgan dysfunction (sepsis syndrome)
    - Invasive fungal infection
    - Hospitalization at the time of fever development
    - Other clinically documented infections
    - Prior episode of febrile neutropenia
- Prophylaxis of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in individuals with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
- Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- Prophylaxis of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
- Prophylaxis of neutropenia in individuals, undergoing hematopoietic cell transplant for any of the following indications**:**
    - Mobilization of hematopoietic progenitor cells in combination with plerixafor in the autologous setting for individuals with non-Hodgkin lymphoma or multiple myeloma
    - Mobilization of donor hematopoietic progenitor cells or for granulocyte transfusion in the allogeneic setting
    - As supportive care in the posttransplant setting
- Mobilization of hematopoietic progenitor cells in hematopoietic cell transplant in the autologous setting for any of the following:
    - As a single agent
    - Following combination chemotherapy
    - In combination with sargramostim
    - In combination with plerixafor for individuals with non-Hodgkin lymphoma or multiple myeloma
- Hematopoietic cell transplant for mobilization of donor hematopoietic progenitor cells or for granulocyte transfusion in the allogeneic setting
- Supportive care for hematopoietic cell transplant in the posttransplant setting

- Treatment of chemotherapy-induced febrile neutropenia for one of the following conditions**:**
    - In individuals who have been receiving prophylactic tbo-filgrastim
    - In individuals who have not received prophylactic granulocyte colony-stimulating factors but who have risk factors for an infection-associated complication
- Treatment for individuals with radiation-induced myelosuppression following a radiological or nuclear incident (hematopoietic acute radiation syndrome [H-ARS]):
- Management of CAR T-Cell-Related toxicities as additional supportive care for neutropenic individuals
- Treatment of individuals with lower risk[†,††] MDS associated with symptomatic anemia with no del(5q), with or without other cytogenetic abnormalities with serum erythropoietin ≤500 mU/mL for any of the following**:**
    - With ring sideroblasts <15% (or ring sideroblasts <5% with an SF3B1 mutation) in combination with an erythropoiesis-stimulating agent (ESA) following no response (despite adequate iron stores) to either an ESA alone or luspatercept-aamt (REBLOZYL)
    - With ring sideroblasts ≥15% (or ring sideroblasts ≥5% with an SF3B1 mutation), in combination with an erythropoiesis-stimulating agent (ESA) following no response to luspatercept-aamt (REBLOZYL)

TBO-FILGRASTIM (GRANIX)

Tbo-filgrastim (Granix) is considered medically necessary and, therefore, covered for any of the following indications:

- May be used as a substitute for filgrastim
- Prophylaxis of severe neutropenia in adult and pediatric individuals 1 month and older with nonmyeloid malignancies receiving myelosuppressive anticancer therapy associated with a clinically significant incidence of febrile neutropenia
- Prophylaxis of chemotherapy-induced febrile neutropenia or other dose-limiting neutropenic events in high-risk (>20% overall risk of febrile neutropenia[†]) individuals with solid tumors and nonmyeloid malignancies receiving treatment in the curative/adjuvant or palliative settings
- Prophylaxis of chemotherapy-induced febrile neutropenia or other dose-limiting neutropenic events in intermediate-risk (10% to 20% overall risk of febrile neutropenia[†]) individuals with solid tumors and nonmyeloid malignancies receiving treatment in the curative/adjuvant or palliative settings who have one or more risk factors
- Prophylaxis of chemotherapy-induced febrile neutropenia or other dose-limiting neutropenic events in low-risk (<10% overall risk of febrile neutropenia) individuals with solid tumors and nonmyeloid malignancies receiving treatment in the curative/adjuvant or palliative settings who have two or more individual-related risk factors.

- Treatment for individuals with radiation-induced myelosuppression following a radiological/nuclear incident (hematopoietic acute radiation syndrome [H-ARS])

- Treatment of chemotherapy-induced febrile neutropenia for one of the following conditions:
    - In individuals who have been receiving prophylactic tbo-filgrastim
    - In individuals who have not received prophylactic granulocyte colony-stimulating factors but who have risk factors for an infection-associated complication

- Treatment of individuals with lower risk[†,††] MDS associated with symptomatic anemia with no del(5q), with or without other cytogenetic abnormalities with serum erythropoietin ≤500 mU/mL and any of the following:
    - In combination with an erythropoiesis-stimulating agent (ESA) following no response (despite adequate iron stores) to either an ESA alone or luspatercept-aamt (REBLOZYL) in individuals with ring sideroblasts <15% (or ring sideroblasts <5% with an SF3B1 mutation)
    - In combination with an ESA following no response to luspatercept-aamt (REBLOZYL) in individuals with ring sideroblasts ≥15% (or ring sideroblasts ≥5% with an SF3B1 mutation)

[†,††]L*ower risk defined as IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate).*

Duration of authorization: 12 months

Version Effective Date: 05/2026

Field Name	Field Description
Prior Authorization Group Description	**Gene Therapy for Regular Red Blood Cell (RBC) Transfusion Dependent Beta-Thalassemia**
Drugs	Casgevy (exagamglogene autotemcel), Zynteglo (betibeglogene autotemcel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Repeat use of same gene therapy agent Trial of a different gene therapy agent after another has been used
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved prescribing information
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment **for one gene therapy agent**.
Other Criteria Revision/Review Date: 2/2026	**<u>Initial Authorization:</u>** • Medication is prescribed at an FDA approved dose • Member has a diagnosis of transfusion dependent beta-thalassemia • Member requires regular RBC transfusions defined as ONE of the following: o History of ≥100 mL/kg/year of packed red blood cell (pRBCs) in the past 2 years o History of ≥8 transfusions of pRBCs per year in the past 2 years • Patient has not had a prior HSCT or gene therapy treatment • If the request is for Zynteglo, a medical reason must be submitted why the patient is unable to use Casgevy • Negative pregnancy test (if applicable) **The safety and effectiveness of repeat administration of Casgevy or Zynteglo have not been evaluated and will not be approved.**

Title: Givosiran (Givlaari) and Panhematin (Hemin)

MEDICALLY NECESSARY:

GIVOSIRAN (GIVLAARI)

Initial Therapy
Initiation of givosiran (Givlaari) is considered medically necessary and, therefore, covered if the following criteria are met:

- Individual is 18 years of age or older
    - Individual has a diagnosis of acute hepatic porphyria, and confirmation of one of the following subtypes:
        - Acute intermittent porphyria (AIP)
        - Hereditary coproporphyria (HCP)
        - Variegate porphyria (VP)
        - Alanine aminotransferase (ALT) dehydratase-deficiency porphyria (ADP)
- Individual has documentation of elevated urinary or plasma porphobilinogen (PBG) or delta-aminolevulinic acid (ALA) within the past year
- Individual meets one of the following criteria:
    - Individual has active symptomatic disease, with at least two documented porphyria attacks within the last 6 months
    - Individual is currently on prophylactic hemin treatment due to history of severe or frequent porphyria attacks

Dosing and Frequency
The recommended dosing for givosiran (Givlaari) by the US Food and Drug Administration (FDA) is 2.5 mg/kg given subcutaneously (SC) once every month by a healthcare provider, and injections are administered in a facility that is equipped and staffed to handle any anaphylactic reactions that may occur.

Continuation Therapy
Continuation of givosiran (Givlaari) is considered medically necessary and, therefore, covered if the following criteria are met:

- Individual has experienced a clinical response to therapy (e.g., a reduction in the number of porphyria attacks, or a reduction in hemin requirements for acute attacks)
- Individual does not have severe or clinically significant transaminase elevations, defined as ALT greater than five times the upper limit of normal.

PANHEMATIN (HEMIN)
Panhematin (Hemin) is considered medically necessary and, therefore, covered for individuals with acute hepatic porphyria when all of the following criteria are met:

- The individual is 16 years of age or older

- The individual has a diagnosis of acute hepatic porphyria, and confirmation of one of the following subtypes:
    - Acute intermittent porphyria (ACP)
    - Hereditary coproporphyria (HCP)
    - Variegate porphyria (VP)
    - ALA dehydratase-deficiency porphyria (ADP)
- The individual has documentation of elevated urinary or plasma PBG, ALA, or total porphyrin prior to receiving treatment
- The individual has presence of clinical symptoms suggestive of acute porphyric attack (e.g., unremitting abdominal pain, neuropathy, paresis, tachycardia)

If the individual has recurrent porphyria attacks (≥4 per year), prophylactic use—with or without the presence of symptoms—is considered medically necessary.

Dosing and Frequency

The recommended dosing for panhematin (Hemin) is 1 to 4 mg/kg/d intravenous (IV) for 3 to 14 days based on the clinical signs. In more severe cases, this dose may be repeated no earlier than every 12 hours.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Golimumab (Simponi Aria®) Intravenous (IV) Injection

MEDICALLY NECESSARY:

INITIAL THERAPY

Ankylosing Spondylitis (AS)

Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the treatment of active AS when all of the following criteria are met:

- The individual is at least 18 years old.
- Documentation of failure, contraindication, or intolerance to either of the following:
    - At least a 4-week trial of two nonsteroidal anti-inflammatory drugs (NSAIDs) at maximum recommended or tolerated anti-inflammatory dose
    - At least a 3-month trial of one disease-modifying antirheumatic drug (DMARD) (e.g., sulfasalazine, methotrexate, hydroxychloroquine)
- Active or latent tuberculosis (TB) has been ruled out.

Immune Checkpoint Inhibitor–Related Toxicities

Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the management of moderate or severe immunotherapy-related inflammatory arthritis when all of the following criteria are met:

- If no improvement after holding immunotherapy and treating with oral corticosteroids, or if unable to taper corticosteroids, or no response to conventional synthetic DMARDs (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)
- Active or latent TB has been ruled out.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the treatment of active pJIA when all of the following criteria are met:

- The individual is at least 2 years old.
- Documentation of failure, contraindication, or intolerance to at least 2 months of one DMARD (e.g., methotrexate)
- Active or latent TB has been ruled out.

Psoriatic Arthritis (PsA)

Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the treatment of active PsA when all of the following criteria are met:

- The individual is at least 2 years old.
- Documentation of failure, contraindication, or intolerance to either of the following:
    - At least a 4-week trial of any NSAIDs at maximum recommended or tolerated anti-inflammatory dose

    - At least a 3-month trial of one DMARD (e.g., methotrexate, hydroxychloroquine, leflunomide, or sulfasalazine)
- Active or latent TB has been ruled out.

Rheumatoid Arthritis (RA)
Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the treatment of moderately to severely active RA in combination with methotrexate (MTX) (or a different DMARD when MTX is contraindicated or the individual is intolerant [e.g., sulfasalazine, hydroxychloroquine, and leflunomide]) when all of the following criteria are met:

- The individual is at least 18 years old.
- The individual has persistent disease despite at least 3 months of MTX.
    - In individuals in whom MTX is contraindicated or the individual is intolerant to MTX, a 3-month trial of a different DMARD (e.g., sulfasalazine, hydroxychloroquine, and leflunomide) is acceptable.
- Active or latent TB has been ruled out.

CONTINUATION THERAPY
Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the continuation therapy when the individual meets all of the following:

- Individual has met the medical necessity criteria for Initial Therapy
- There is documentation of positive clinical response or stabilization to therapy (e.g., improvement in total active [swollen and tender] joint count from baseline, or improvement in symptoms [e.g., pain, stiffness, inflammation] from baseline)

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: Guselkumab (Tremfya®) Injection for Intravenous Use

MEDICALLY NECESSARY:

ULCERATIVE COLITIS

Guselkumab (Tremfya) for intravenous (IV) infusion is considered medically necessary and, therefore, covered for the treatment of individuals with moderate-to-severe active ulcerative colitis when both of the following criteria and the Dosing and Frequency Requirements listed below are met:

- The individual is at least 18 years of age.
- There is documentation of inadequate response, lost response, or intolerance to a trial of one of the following:
    - Immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate)
    - Demonstrated dependence on corticosteroids (e.g., budesonide [Entocort EC], prednisone, hydrocortisone, methylprednisolone)
    - Tumor necrosis factor (TNF) blocker (e.g., adalimumab Humira®)
    - Biologics for the treatment UC (e.g., ustekinumab (Stelara), risankizumab (Skyrizi), golimumab (Simponi®)
    - JAK Inhibitors (e.g., tofacitinib [Xeljanz], upadacitinib [Rinvoq])
- No concurrent use with any other biologic therapy (i.e., tumor necrosis factor antagonists)
- Prescribed by or in consultation with a gastroenterologist
- Dosing and frequency: IV infusion will be used as an induction dose, followed by maintenance dosing with subcutaneous (SC) injection
    - Induction: IV: 200 mg on weeks 0, 4, and 8 followed by maintenance (Tremfya SC)

Note: The duration of Guselkumab (Tremfya) IV infusion is limited to 3 doses.

Duration of authorization: 12 months

Version Effective Date: 2/2026

Title: Imetelstat (Rytelo™)

MEDICALLY NECESSARY:

INITIAL THERAPY

Imetelstat (Rytelo™) is considered medically necessary and, therefore, covered for the treatment of adult individuals with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia when dosing and frequency requirements and **ALL** of the following criteria are met:

- Diagnosis of MDS confirmed by bone marrow aspirate and/or biopsy
- Individual has required transfusion of 4 or more red blood cell (RBC) units over 8 weeks **AND** pretransfusion hemoglobin is 9.0 g/dL or less
- Individual with lower risk disease (i.e., very low, low, intermediate) as assessed by validated rating index/scale (e.g., International Prognostic Scoring System-revised [IPSS-R]) and **ONE** of the following:
    - Disease associated with symptomatic anemia **WITH** del(5q), with or without one other cytogenetic abnormality (except those involving chromosome 7) and **ONE** of the following:
        - Following no response to or relapse after lenalidomide if poor probability to respond to immunosuppressive therapy (IST) (e.g., older age, high-risk mutations)
        - Following no response to or relapse after an erythropoiesis-stimulating agent (ESA) if poor probability to respond to IST (e.g., older age, high-risk mutations)
        - Following no response to or relapse after lenalidomide, followed by no response to or intolerance or relapse after IST
        - Following no response to or relapse after an ESA with serum erythropoietin 500 mU/mL or less, followed by no response to or intolerance or relapse after IST
    - Disease associated with symptomatic anemia **WITHOUT** del(5q), with or without other cytogenetic abnormalities and **ONE** of the following:
        - With ring sideroblasts less than 15 percent (or ring sideroblasts less than 5 percent with an SF3B1 mutation) and **ONE** of the following:
            1. With serum erythropoietin 500 mU/mL or less following no response to or relapse after an ESA alone, followed by no response to or relapse after an ESA with or without a G-CSF or lenalidomide
            2. With serum erythropoietin 500 mU/mL or less following no response to or relapse after an ESA alone, followed by no response to or relapse after luspatercept-aamt
            3. With serum erythropoietin 500 mU/mL or less following no response to or relapse after luspatercept-aamt, followed by no

response to or relapse after an ESA with or without a G-CSF or lenalidomide
4. With serum erythropoietin greater than 500 mU/mL and a poor probability to respond to IST (e.g., older age, high-risk mutations)
5. With serum erythropoietin greater than 500 mU/mL following no response to or intolerance or relapse after IST

- With ring sideroblasts 15 percent or greater (or ring sideroblasts 5 percent or greater with an SF3B1 mutation) and **ONE** of the following:
  1. Following no response to or relapse after luspatercept-aamt (National Comprehensive Cancer Network [NCCN] preferred)
  2. With serum erythropoietin 500 mU/mL or less following no response to or relapse after luspatercept-aamt, followed by no response to or relapse after an ESA with or without a G-CSF if a poor probability to respond to IST (e.g., older age, high-risk mutations)
  3. With serum erythropoietin 500 mU/mL or less following no response to or relapse after luspatercept-aamt, followed by no response to or relapse after an ESA with or without a G-CSF, followed by no response to or intolerance or relapse after IST
  4. As initial treatment if serum erythropoietin greater than 500 mU/mL (ineligible for ESAs)
  5. With serum erythropoietin greater than 500 mU/mL following no response to or relapse after luspatercept-aamt, followed by no response to or relapse after lenalidomide if a poor probability to respond to IST (e.g., older age, high-risk mutations)
  6. With serum erythropoietin greater than 500 mU/mL following no response to or relapse after luspatercept-aamt, followed by no response to or relapse after lenalidomide, followed by no response to or intolerance or relapse after IST

- Dosing and frequency: 7.1 mg/kg administered as an intravenous infusion over 2 hours every 4 weeks

CONTINUATION THERAPY

Continuation of imetelstat (Rytelo) is considered medically necessary and, therefore, covered for individuals who have demonstrated **BOTH** of the following, compared to baseline:

- Individual experiences a decrease in RBC transfusion burden after 24 weeks of treatment (administration of 6 doses)
- No unacceptable toxicity occurs at any time

Duration of authorization: 12 months

Version Effective Date: 05/2026

Field Name	Field Description
Prior Authorization Group Description	**Immune Globulins**
Drugs	Gamunex-C (IV or SQ) (Immune Globulin) Bivigam (IV) (Immune Globulin) Cuvitru (SQ) (Immune Globulin) Flebogamma (IV) (Immune Globulin) Gammagard liquid (IV or SQ) (Immune Globulin) Gammagard SD (IV) (Immune Globulin) Gammaked (IV or SQ) (Immune Globulin) Gammaplex (IV) (Immune Globulin) Hizentra (SQ) (Immune Globulin) Octagam (IV) (Immune Globulin) Privigen (IV) (Immune Globulin) Asceniv (IV) (Immune Globulin-slra) Cutaquig (SQ) (Immune Globulin-hipp) Panzyga (IV) (Immune Globulin-ifas) Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase) Xembify (SQ) (Immune Globulin-klhw) Alyglo (IV) (Immune Globulin-stwk) Or any newly marketed immune globulin ****Gamunex-C is the preferred product for the indications of primary immunodeficiency, chronic idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met the request will be approved for a 3 month duration unless otherwise specified in the diagnosis specific “Other Criteria” section below.
Other Criteria	**All Requests:** • Documentation of diagnosis confirmed by a specialist • Member has tried and failed, or has a documented medical reason for not using, all other standard of care therapies as defined per recognized guidelines • Member’s height and weight are provided

	• Dosing will be calculated using ideal body weight (IBW), unless ONE of the following:
	  o If the member's actual weight is less than their IBW, then dosing will be calculated using their actual weight
	  o If the member's body mass index (BMI) is ≥30 kg/m^2 OR if their actual weight is greater than 20% of their IBW, then dosing will be calculated using adjusted body weight (adjBW)
	
	Primary Immunodeficiency*:
	• Patient's IgG level is provided and below normal for requested indication, or a documented specific antibody deficiency is provided
	• Clinically significant deficiency of humoral immunity as evidenced by ONE of the following:
	  o Inability to produce an adequate immunologic response to specific antigens.
	  o History of recurrent infections despite prophylactic antibiotics
	• Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
	• If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
	
	• If criteria is met, approve for 6 months.
	
	*Primary Immunodeficiency includes, but is not limited to, the following: Congenital agammaglobulinemia, hypogammaglobulinemia (Common Variable Immunodeficiency, CVID), severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome, X-linked agammaglobulinemia or Bruton's agammaglobulinemia, hypergammaglobulinemia, X-linked hyper IgM syndrome
	
	Idiopathic Thrombocytopenic Purpura, acute and chronic:
	• Acute:
	  o Patient has active bleeding, requires an urgent invasive procedure, is deferring splenectomy, has platelet counts < 20,000/ul and is at risk for intra-cerebral hemorrhage or has life threatening bleeding, or has an inadequate increase in platelets from corticosteroids or is unable to tolerate corticosteroids
	  o Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days
	• Chronic:
	  o Duration of illness is greater than 12 months
	  o Member has documented trial and failure of corticosteroids and splenectomy, or has a documented medical reason why they are not able to use

	corticosteroids or member is at high risk for post-splenectomy sepsis. o Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days • If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C • If criteria is met, approve for up to 5 days. **<u>Kawasaki disease</u>:** • Immunoglobulin is being given with high dose aspirin unless contraindicated • Requested dose does not exceed a single 2g/kg dose • If criteria is met, approve for 1 dose **<u>Chronic B-cell lymphocytic leukemia</u>:** • The patient has had recurrent infections requiring IV antibiotics or hospitalization and has a serum IgG of <500 mg/dL • Dose does not exceed 500mg/kg every 3-4 weeks • If criteria is met, approve for 3 months. **<u>Bone marrow transplantation:</u>** • The patient has bacteremia or recurrent sinopulmonary infections and their IgG level is < 400mg/dL • Dose does not exceed 500mg/kg/wk for the first 100 days post-transplant • Dose does not exceed 500 mg//kg every 3-4 weeks 100 days after transplant • If criteria is met, approve for 3 months. **<u>Pediatric HIV</u>**: • Patient is < 13 years of age • Either patient's IgG level is < 400mg/dL or • If patient's IgG level is ≥ 400 mg/dL than significant deficiency of humoral immunity as evidenced by ONE of the following: o Inability to produce an adequate immunologic response to specific antigens. o History of recurrent bacterial infections despite prophylactic antibiotics • Dose does not exceed 400mg/kg/dose every 2-4 weeks • If criteria is met, approve for 3 months. **<u>Multifocal motor neuropathy (MMN)</u>**:

	• Duration of symptoms has been at least 1 month with disability.
	• Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN.
	• Dose does not exceed 2.4 g/kg/month administered over 2 to 5 days.
	
	• If criteria is met, approve for up to 5 days for 6 months.
	
	<u>Chronic inflammatory demyelinating polyneuropathy (CIDP)</u>:
	• Duration of symptoms has been at least 2 months with disability.
	• Nerve conduction studies or a nerve biopsy were completed in order to rule out other possible conditions, and confirms the diagnosis of CIDP.
	• Patient has tried and failed, or has a documented medical reason for not using, corticosteroids.
	  o If the patient has severe and fulminant or pure motor CIDP a trial of corticosteroids is not required
	• Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
	• If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
	
	<u>Guillain-Barre syndrome</u>:
	• Patient has severe disease with the inability to walk without aid
	• Onset of symptoms within the last 4 weeks
	• Dose does not exceed 2g/kg administered over 2-5 days
	
	• If criteria is met, approve for up to 5 days.
	
	<u>Myasthenia Gravis:</u>
	• <u>Acute:</u>
	  o Patient has an acute myasthenic exacerbation (i.e. acute episode of respiratory muscle weakness, difficulty swallowing, etc.) or is in preparation for thymoma surgery to prevent myasthenic exacerbation
	  o Dose does not exceed 2 g/kg administered over 2-5 days
	  o If criteria is met, approve for up to 5 days
	• <u>Chronic:</u>
	  o Diagnosis of refractory generalized myasthenia gravis
	  o Patient has tried and failed, or has a documented medical reason for not using 2 or more immunosuppressive therapies (i.e. corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil)
	  o Dose does not exceed 2 g/kg/month administered over 2-5 days
	  o If criteria is met, approve for 3 months

Revision/Review Date 2/2026	**Dermatomyositis (DM):**
	• One of the following:
	  o Bohan and Peter score of 3 (i.e. definite DM)
	  o Bohan and Peter score of 2 (i.e. probable DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist)
	• Patient does NOT have any of the following:
	  o Cancer (CA) associated myositis defined as myositis within 2 years of CA diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cure)
	  o Active malignancy
	  o Malignancy diagnosed within the previous 5 years
	  o Breast CA within the previous 10 years
	• For a diagnosis of DM, one of the following:
	  o Member has tried and failed, or has a documented medical reason for not using both of the following:
	  ▪ methotrexate (MTX) OR azathioprine
	  ▪ rituximab.
	  o Member has severe, life-threatening weakness or dysphagia
	• For a diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM):
	  o Member has tried and failed, or has a documented medical reason for not using all of the following: MTX and mycophenolate mofetil.
	• Dose does not exceed 2 g/kg administered over 2-5 days every 4 weeks.
	• If criteria is met, approve for up to 3 months.
	
	If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a Medical Director/Clinical reviewer for medical necessity review.
	
	Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary

Title: Inclisiran (Leqvio®)

MEDICALLY NECESSARY:

1. **Criteria for Initial Approval**
   Inclisiran (Leqvio) is considered medically necessary and, therefore, covered for the treatment of hypercholesterolemia in adults when *one* (A or B) of the following criteria are met:
   A. Individual meets ALL of the following:

- Individual has a history of clinical atherosclerotic cardiovascular disease (ASCVD) *(see Section A in the GUIDELINES portion of this medical policy bulletin)*; *and*
- Individual meets *one* of the following:

-- Current LDL-C level greater than or equal to 55 mg/dL after at least three months of treatment with a high-intensity statin. If the individual is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used; *or*

-- Current LDL-C level greater than or equal to 55 mg/dL with a contraindication or intolerance to statins *(see SECTIONS B & C in the GUIDELINES portion of this medical policy bulletin)*; *and*

B. Individual meets ALL of the following:

- Individual had an untreated (before any lipid-lowering therapy) LDL-C level greater than or equal to 190 mg/dL in the absence of a secondary cause; *and*
- Individual meets *one* of the following:

-- Current LDL-C level greater than or equal to 100 mg/dL after at least three months of treatment with a high-intensity statin. If the individual is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used; *or*
-- Current LDL-C level greater than or equal to 100 mg/dL with a contraindication or intolerance to statins *(see SECTIONS B & C in the GUIDELINES portion of this medical policy bulletin)*; *and*

2. Continuation of Therapy
Continuation of inclisiran (Leqvio) therapy is considered medically necessary in individuals who have an indication and associated factor(s) & presentation(s) listed in Section I above when ALL of the following criteria are met:

Individual has achieved or maintained an LDL-C reduction (e.g., LDL-C is now at goal, clinically acceptable lowering of LDL-C)
Guidelines

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, Inclisiran (Leqvio®) is covered under the medical benefits of the Company's products when the medical necessity criteria listed in this medical policy are met.

U.S. Food and Drug Administration (FDA)-Approved Indications

Initial Approval (December 22, 2021):
Leqvio is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).

Updated Label/Approval (July 2023):
Leqvio is indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).

Updated Label/Approval (July 2025)
Leqvio is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

Section A - Clinical ASCVD

- Acute coronary syndromes
- Myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization procedure (e.g., percutaneous coronary intervention [PCI], coronary artery bypass graft [CABG] surgery)
- Stroke of presumed atherosclerotic origin
- Transient ischemic attack (TIA)
- Non-cardiac peripheral arterial disease (PAD) of presumed atherosclerotic origin (e.g., carotid artery stenosis, lower extremity PAD)
- Obstructive coronary artery disease (defined as fifty percent or greater stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary Artery Calcium (CAC) Score ≥ 1000

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: Inebilizumab-cdon (Uplizna)

MEDICALLY NECESSARY:

INITIAL CRITERIA

Inebilizumab-cdon (Uplizna) is considered medically necessary and, therefore, covered for the treatment of adult individuals with neuromyelitis optica spectrum disorder (NMOSD), when all of the following criteria are met:

- The individual has a diagnosis of NMOSD.
- The individual is anti-aquaporin-4 (AQP4) antibody seropositive.
- The individual has a history of one or more relapses that required rescue therapy within the year or two or more relapses that required rescue therapy in the past two years.
    -

Inebilizumab-cdon (Uplizna) is considered medically necessary and, therefore, covered for the treatment of adult individuals with Immunoglobulin G4-related disease (IgG4-RD), when all of the following criteria are met:

- The individual has a diagnosis of IgG4-RD affecting ≥2 organs/sites at any time
- The individual is experiencing (or recently experienced) an IgG4-RD flare that requires initiation or continuation of glucocorticoids (GC) treatment and/or recurrent disease
- The individual is refractory to or unable to use GC
- Inebilizumab-cdon (Uplizna) will not be used in combination with rituximab

Inebilizumab-cdon (Uplizna) is considered medically necessary and, therefore, covered for the treatment of adult individuals with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive, when all of the following criteria are met:

- The individual has a diagnosis of gMG with a positive serological test for anti–AChR or anti–MuSK antibodies
- The individual has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II to IV
- Individual has an MG-ADL total score ≥6

CONTINUATION CRITERIA

Inebilizumab-cdon (Uplizna) is considered medically necessary for continued use in adult individuals with a diagnosis of NMOSD, IgG4-RD, or gMG when the initial criteria are met AND there is documentation of a positive clinical response (e.g., reductions in relapse or reduction in new onset of symptoms).

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Interleukin-5 (IL-5) Antagonist (e.g., Cinqair®)

MEDICALLY NECESSARY:

INITIAL THERAPY

Reslizumab (Cinqair) is considered medically necessary and, therefore, covered for the treatment of severe eosinophilic asthma when all of the following criteria are met:

- The individual is 18 years of age or older
- Blood eosinophils of at least 400 cells/microliter* at the initiation of treatment (within 3-4 weeks of the first dose)
- The individual is currently receiving treatment that does not maintain adequate control of his/her asthma and reslizumab (Cinqair) is being used as additional maintenance therapy.
    - Current treatment must include high-dose inhaled corticosteroids (ICS) (with or without oral corticosteroids) plus an additional controller (e.g., long-acting beta agonist [LABA], leukotriene inhibitor, theophylline) medication, unless the individual is intolerant of or has a contraindication to these agents.
- Reslizumab (Cinqair) will not be used in combination with other biologics for asthma/allergic conditions (e.g., benralizumab [Fasenra], dupilumab [Dupixent], mepolizumab [Nucala], omalizumab [Xolair])

The dosage, frequency, and route of administration of reslizumab (Cinqair) is 3 mg/kg once every 4 weeks by intravenous infusion.

* Note: 1 microliter is equal to 1 cubic millimeter (mm^3)

CONTINUATION THERAPY

Reslizumab (Cinqair) is considered medically necessary and, therefore, covered during continuation therapy for individuals when there is documentation of clinical improvement in respiratory function (e.g., oral corticosteroid elimination or reduction, exacerbation elimination or reduction, reduced absenteeism from school or work) and when reslizumab (Cinqair) will not be used in combination with other biologics for asthma/allergic conditions (e.g., benralizumab [Fasenra], dupilumab [Dupixent], mepolizumab [Nucala], omalizumab [Xolair])

Duration of authorization: 12 months

Version Effective Date: 2/2026

Title: Intravenous (IV) Iron Preparations

MEDICALLY NECESSARY:

COMPANY-DESIGNATED PREFERRED PRODUCTS
Although there are many brands of intravenous (IV) iron products on the market for the treatment of iron deficiency (ID) or iron-deficiency anemia (IDA), there is no reliable evidence of the superiority of any one brand of IV iron product compared with other brands. The Company has designated the following as its preferred IV iron products for use in adult individuals aged 18 years and older who are treatment-naïve:

- Ferumoxytol (e.g., Feraheme®)
- Sodium ferric gluconate complex in sucrose (e.g., Ferrlecit®)
- Iron dextran (e.g., INFeD®)
- Iron sucrose (e.g., Venofer®)

Ferumoxytol (e.g., Feraheme), sodium ferric gluconate complex in sucrose (e.g., Ferrlecit), iron dextran (e.g., INFeD), and iron sucrose (e.g., Venofer) are less costly and at least as likely to produce equivalent therapeutic results as the non-preferred IV iron products, which include, but are not limited to, ferric carboxymaltose (Injectafer®), and ferric derisomaltose (Monoferric®).

NON-PREFERRED PRODUCTS
The Company has designated the following as its non-preferred IV iron products for use in adult individuals aged 18 years and older:

- Ferric carboxymaltose (Injectafer)
- Ferric derisomaltose (Monoferric)

For individuals who meet the medically necessary criteria below, use of non-preferred IV iron products (which include, but are not limited to, ferric carboxymaltose [Injectafer], ferric derisomaltose [Monoferric]) is considered medically necessary and, therefore, covered when the individual has a documented intolerance, contraindication, or nonresponse to at least two preferred IV iron preparations (i.e., ferumoxytol [e.g., Feraheme], sodium ferric gluconate complex in sucrose [e.g., Ferrlecit], iron dextran [e.g., INFeD], iron sucrose [e.g., Venofer]).

Management of Heart Failure
The use of ferric carboxymaltose (Injectafer) for the treatment of adult individuals with New York Heart Association class II/III heart failure is considered medically necessary and, therefore, covered without the need to try any preferred IV iron products, to improve exercise capacity.

Management of Iron Deficiency (ID) or Iron Deficiency Anemia (IDA) Without Chronic Kidney Disease (CKD)
The use of a non-preferred IV iron product for the treatment of ID or IDA without CKD is considered medically necessary and, therefore, covered for adult individuals with **ALL** of the following:

- Individual has met the requirements listed in the COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections above
- Diagnosis of anemia based on hemoglobin (hgb) below normal levels for individual's age and sex (if using to treat IDA)
- Ferritin level <30 ng/mL **OR** transferrin saturation (TSAT) <20 percent
- Normal kidney function as demonstrated by laboratory values (e.g., urine albumin, creatinine, glomerular filtration ratio [GFR])
- Documented intolerance, contraindication, or nonresponse to oral iron supplementation for at least 3 months

Management of Iron Deficiency (ID) or Iron Deficiency Anemia (IDA) With Chronic Kidney Disease (CKD)

The use of a non-preferred IV iron product for the treatment of ID or IDA with CKD is considered medically necessary and, therefore, covered for adult individuals with **ALL** of the following:

- Individual has met the requirements listed in the COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections above
- Diagnosis of anemia based on hgb below normal levels for individual's age and sex (if using to treat IDA)
- **ONE** of the following:
    - Ferritin level 100 ng/mL or less **AND** TSAT <20 percent in nondialysis individuals or those receiving peritoneal dialysis
    - Ferritin level 200 ng/mL or less **AND** TSAT <20 percent in individuals on hemodialysis
- CKD as demonstrated by abnormal laboratory values (e.g., urine albumin, creatinine, GFR)
- Documented intolerance, contraindication, or nonresponse to oral iron supplementation for at least 3 months

Management of Cancer- and Chemotherapy-Induced Anemia

The use of a non-preferred IV iron product for the treatment of cancer- and chemotherapy-induced anemia is considered medically necessary and, therefore, covered for adult individuals who have met the requirements listed in the COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections above, and with **EITHER** of the following:

- For the treatment of **EITHER** of the following:
    - Absolute iron deficiency (ferritin <30 ng/mL and transferrin saturation <20 percent)
    - Possible functional iron deficiency (ferritin >500–800 ng/mL and transferrin saturation <50 percent) in selected individuals (with the goal of avoiding allogeneic transfusion)
- In combination with erythropoiesis-stimulating agents (ESAs) for the treatment of **EITHER** of the following:

- Functional iron deficiency (ferritin 30–500 ng/mL and transferrin saturation <50 percent) in individuals receiving myelosuppressive chemotherapy without curative intent and ESAs
- Absolute iron deficiency (ferritin <30 ng/mL and transferrin saturation <20 percent) in individuals who do not experience an increase in hemoglobin after 4 weeks of IV or oral iron supplementation

Duration of authorization: 12 months

Version Effective Date: 2/2026

Title: Intravenous Infliximab and Related Biosimilars

MEDICALLY NECESSARY:

Intravenous infliximab (Remicade) and related biosimilars (e.g., unbranded infliximab , infliximab-abda [Renflexis], infliximab-axxq [Avsola], infliximab-dyyb [Inflectra], infliximab-qbtx [Ixifi]) are considered medically necessary and, therefore, covered when the individual meets all of the requirements in the following sections:

- Dosing and frequency requirements listed in Attachment A
- Indications and all the criteria are met

RHEUMATOLOGIC CONDITIONS

- **Ankylosing spondylitis and nonradiographic axial spondyloarthritis**
    - When all of the following criteria are met:
        - Individual is over 18 years of age with evidence of active disease (increasing inflammation, pain, disability, and decreased function)
        - Documentation of an adequate therapeutic trial* of at least two nonsteroidal anti-inflammatory drugs (NSAIDs) that have failed to control symptoms

            *An adequate therapeutic trial is defined as: Treatment with NSAIDs for at least 3 months at maximum recommended or tolerated anti-inflammatory dose unless treatment is discontinued due to lack of response, intolerance, toxicity or contraindication
    - If the above criteria are not met, there must be documentation both of very severe disease and that the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform activities of daily living [ADLs], or severe impact on quality of life)
- **Autoimmune collagen vascular disease**
    - Consideration may be given for individuals with an autoimmune collagen vascular disease that is refractory to conventional therapies.
- **Behçet syndrome**
    - Documented failure, contraindication or intolerance to conventional therapy, such as: corticosteroids, colchicine, or disease-modifying antirheumatic drugs (DMARDs) (e.g., azathioprine [AZA], cyclosporine, other tumor necrosis factor [TNF] inhibitors)
- **Inflammatory bowel disease arthritis**
    - When all of the following criteria are met:
        - Individual is over 18 years of age with evidence of active disease (increased disease activity evidenced by increasing inflammation, pain, disability, and decreased function)

        - Documented failure, contraindication or intolerance to a 3-month trial of any of the DMARDs (e.g., sulfasalazine, AZA, methotrexate, other anti-TNF agents)
    - If the above criteria are not met, there must be documentation of very severe disease and the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform ADLs, or severe impact to quality of life)
- **Polyarticular juvenile idiopathic arthritis (JIA)**
    - When all of the following criteria are met:
        - Individual is 4 years of age and older with moderate-to-severe polyarticular JIA with evidence of active disease (increased disease activity evidenced by increasing inflammation, pain, disability, and decreased function)
        - Documented failure, contraindication, or intolerance to a 3-month trial of any of the nonbiologic DMARDs (e.g., methotrexate, sulfasalazine, leflunomide)
        - Documented failure, contraindication, or intolerance to a 3-month trial of any of the US Food and Drug Administration (FDA)-approved biologic DMARDs for JIA (e.g., anti-TNF, T-cell costimulation modulators)
        - Infliximab or related biosimilars will be used in combination with methotrexate, or as a monotherapy when the individual is intolerant of, or has a contraindication to, methotrexate
    - If the above criteria are not met, there must be documentation of both very severe disease and that the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform ADLs, or severe impact on quality of life)
- **Psoriatic arthritis**
    - When all the following criteria are met:
        - Individual is over 18 years of age with evidence of active disease (increased disease activity evidenced by increasing inflammation, pain, disability, and decreased function)
        - Documented failure, contraindication or intolerance to a 3-month trial of any of the DMARDs (e.g., sulfasalazine, AZA, cyclosporine, methotrexate, other anti-TNF agents)
    - If the above criteria are not met, there must be documentation both of very severe disease and that the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform ADLs, or severe impact to quality of life)
- **Reactive arthritis (Reiter disease)**
    - When all the following criteria are met:
        - Individual is over 18 years of age with evidence of active disease (increased disease activity evidenced by increasing inflammation, pain, disability, and decreased function)

        - Documented failure, contraindication, or intolerance to a 3-month trial of any of the DMARDs (e.g., sulfasalazine, methotrexate, other anti-TNF agents)
    - If the above criteria are not met, there must be documentation of very severe disease and the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform ADLs, or severe impact to quality of life)
- **Rheumatoid arthritis (RA)**
    - When all the following criteria are met:
        - Individual is over 18 years of age with moderate-to-severe rheumatoid arthritis with evidence of active disease (increased disease activity evidenced by increasing inflammation, pain, disability, and decreased function)
        - Documented failure, contraindication or intolerance to a 3-month trial of any of the DMARDs (e.g., hydroxychloroquine, leflunomide, sulfasalazine, methotrexate, other anti-TNF agents or non-TNF biologics [abatacept, rituximab, tocilizumab])
        - Infliximab or related biosimilars will be used in combination with methotrexate, or as a monotherapy when the individual is intolerant of, or has a contraindication to, methotrexate
    - If the above criteria are not met, there must be documentation both of very severe disease and that the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform ADLs, or severe impact on quality of life)
- **Sarcoidosis**
    - When both criteria are met:
        - Individual at least 18 years of age
        - Documentation of failure, contraindication or intolerance to a 3-month trial of a standard regimen of corticosteroids and DMARDs (e.g., methotrexate, AZA)
    - If the above criteria are not met, there must be documentation both of very severe disease and that the professional provider considers infliximab or related biosimilars to the best initial drug of choice with appropriate justification (disability, and inability to perform ADLs, or severe impact on quality of life)
- **Uveitis, noninfectious, due to Behçet syndrome**
    - Documented diagnosis of Behçet disease with vision-threatening uveitis
- **Uveitis, noninfectious, not due to Behçet syndrome**
    - Documented failure, contraindication or intolerance to corticosteroids and at least one DMARD (e.g., AZA, cyclosporine, methotrexate, mycophenolate, tacrolimus, or other TNF inhibitors)

GASTROINTESTINAL INDICATIONS

- **Crohn disease (CD): nonfistulizing**
    - Presence of moderately to severely active CD in adults or pediatric individuals 6 years of age or older when **all** the following criteria are met:
        - The individuals has active CD as indicated by any of the following signs or symptoms: gastrointestinal bleeding, weight loss, diarrhea, perianal disease, internal fistula(ae), intestinal obstruction, megacolon or extraintestinal manifestations, such as arthritis or spondylitis
        - The individual has had an inadequate response to conventional therapies (unless intolerant or contraindicated) that include, but are not limited to: antibiotics, 5-aminosalicylates (e.g., mesalamine), DMARDs (e.g., 6-mercaptopurine [6-MP], AZA, corticosteroids)
    - Presence of severe inflammatory disease involving the distal small bowel and/or large bowel in an individual who is having symptoms of gastrointestinal bleeding, diarrhea, profound anemia, and poor nutritional intake associated with weight loss and abdominal pain.
- **Crohn disease: fistulizing**
    - When both criteria are met:
        - An adult or pediatric individual 6 years of age or older whose presentation of CD involves the formation of a fistula(ae)
        - An adult or pediatric individual 6 years of age or older with diffuse inflammatory disease involving the distal small bowel and/or large bowel who is having symptoms of profound anemia, gastrointestinal bleeding, poor nutritional intake associated with weight loss, and abdominal pain
- **Ulcerative colitis: adults**
    - When all the following criteria are met:
        - In individuals 18 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy, including a documented failure, contraindication, or intolerance to at least two of the following:
            - Aminosalicylates: (e.g., mesalamine [Apriso, Asacol, Canasa, Lialda, Pentasa, Rowasa], sulfasalazine [Azulfidine], olsalazine [Dipentum])
            - Systemic corticosteroids: (e.g., prednisone, prednisolone)
            - DMARDs (e.g., 6-MP, AZA [Imuran], or cyclosporine [e.g., Neoral, Gengraf])

    OR

    - When either of the following criteria are met:
        - In individuals 18 years of age or older, when there is a clinical presentation that requires an intervention with a more immediate effect to resolve the colitis; examples include:
            - Symptoms of profound anemia, poor nutritional intake associated with weight loss, and abdominal pain

        - Individuals who have the potential for adverse events to the other, more common treatment regimens or who have contraindication to the use of these treatment regimens (e.g., individuals with underlying diabetes may have worsening control with the addition of prednisone)
    - If the above criteria are not met, there must be documentation of the individual's rapidly worsening disease as indicated by increasing disability, poorly controlled symptoms, and increasing quality of life concerns (cannot perform ADLs without great difficulty) and there is inadequate response to more conventional agents.
- **Ulcerative colitis: children**
    - When all of the following criteria are met:
        - Child is at least 6 years of age
        - Has moderately to severely active ulcerative colitis (see Policy Guidelines section)
        - Has had an inadequate response to conventional therapy, e.g., aminosalicylates, AZA (Imuran), 6-MP, or corticosteroids

DERMATOLOGIC INDICATIONS

- **Hidradenitis suppurativa**
    - When all of the following criteria are met:
        - The individual is 18 years of age or older with documentation of moderate to severe hidradenitis suppurativa with recurrent abscesses/inflammatory nodules and scar formation.
        - Documentation of failure, contraindication, or intolerance to at least 3 months of antibiotics (e.g., doxycycline, clindamycin, rifampin).
        - Documentation of failure, contraindication, or intolerance to a 3-month trial of any of the FDA-approved biologic DMARDs for hidradenitis suppurativa (e.g., anti-TNF agents, T-cell costimulation modulators)**.**
- **Plaque psoriasis**
    - When all the following criteria are met:
        - The individual is 18 years of age or older with chronic, severe psoriasis who is a candidate for systemic therapy but other systemic therapies are less medically appropriate (e.g., presence of other factors such as hypertension, alcohol consumption, the condition of pregnancy, nonmelanoma skin cancers).
        - Individual is affected with plaque psoriasis covering more than 10% of body surface area (BSA) or a lesser percentage if psoriasis affects sensitive body areas, such as hands, feet, face, or genitals.
        - Documentation of failure, contraindication, or intolerance to a trial of at least 3 months with at least one of the following:
            - Phototherapy: either ultraviolet-B or psoralen/ultraviolet A (PUVA)
            - Methotrexate (e.g., Trexall, Rheumatrex)

        - Retinoids (e.g., acitretin [Soriatane])
        - Cyclosporine (e.g., Neoral, Gengraf)
    - If the above criteria are not met, there must be documentation of severe psoriasis (>10% BSA) or a lesser percentage if psoriasis affects sensitive body areas, such as hands, feet, face, or genitals and is very symptomatic (e.g., pain, pruritus, burning, scaling), the symptoms significantly hinder the quality of life, and the use of other systemic therapy is not appropriate due to other factors (e.g., history of hypertension, alcohol consumption, the condition of pregnancy, nonmelanoma skin cancers).
- **Pyoderma gangrenosum**
    - In individuals 18 years of age or older with documentation of pyoderma gangrenosum that is refractory to a 3-month trial of conventional treatments, such as local steroid injections, topical tacrolimus, systemic corticosteroids, dapsone, DMARDs (e.g., cyclosporine), and conservative wound care, including oral antibiotics
    - If the above criterion is not met, there must be documentation of rapidly worsening disease process as indicated by increasing disability, poorly controlled symptoms, and increasing quality of life concerns (cannot perform ADLs without great difficulty) and who is not adequately responding to more conventional agents.

HEMATOPOIETIC CELL TRANSPLANTATION

- **Acute Graft-Versus Host Disease (aGVHD)**
    - Acute GVHD in those who have undergone hematopoietic cell transplantation, as additional therapy in conjunction with systemic corticosteroids and in combination with original immunosuppressive agent (i.e., tacrolimus, cyclosporine, methotrexate) following no response (steroid-refractory disease) to first-line therapy options

IMMUNOTHERAPY-RELATED TOXICITY INDICATIONS

- Treatment of any of the following immunotherapy-related toxicities as additional immunosuppression
    - Cardiac toxicities
        - In individuals with myocarditis if no improvement within 24 to 48 hours of starting pulse-dose methylprednisolone
    - Esophagitis
        - In individuals with moderate to severe esophagitis, gastritis, or duodenitis if no improvement on corticosteroids or budesonide
    - Diarrhea or colitis
        - In individuals with mild (Grade 1) diarrhea and colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin

        - In individuals with moderate (Grade 2) or severe (Grades 3–4) diarrhea or colitis if colonoscopy or flexible sigmoidoscopy shows significant ulceration or extensive nonulcerative inflammation
    - Anemia
        - In individuals with G4 hemolytic anemia with hemolysis if no response to corticosteroids and rituximab
    - Elevated serum creatinine/acute renal injury
        - In individuals with severe (Stage 3) (creatinine >3 times baseline or >4 mg/dL) elevated serum creatinine/acute kidney injury toxicity remains greater than Stage 2 after 4 to 6 weeks of corticosteroids or if creatinine increases during steroid taper (or once off corticosteroids)
    - Inflammatory arthritis
        - In individuals with moderate or severe inflammatory arthritis unable to taper corticosteroids after 1 week
    - Pneumonitis
        - In individuals with moderate (G2) pneumonitis if no improvement after 48 to 72 hours of corticosteroids or severe (Grades 3–4) pneumonitis who show no improvement after 48 hours methylprednisolone).
    - Uveitis
        - In individuals with G1-4 uveitis that is refractory to high-dose systemic corticosteroids (treatment guided by ophthalmology)

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Intravenous Infliximab and Related Biosimilars

MEDICALLY NECESSARY:

DOSING AND FREQUENCY REQUIREMENTS FOR INTRAVENOUS INFLIXIMAB (REMICADE) AND RELATED BIOSIMILARS (E.G., UNBRANDED INFLIXIMAB, INFLIXIMAB-ABDA [RENFLEXIS], INFLIXIMAB-AXXQ [AVSOLA], INFLIXIMAB-DYYB [INFLECTRA], INFLIXIMAB-QBTX [IXIFI])

The Company reserves the right to modify the Dosing and Frequency Requirements listed in this Policy to ensure consistency with the most recently published recommendations for the use of infliximab and related biosimilars. Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to: the US Food and Drug Administration (FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of infliximab or related biosimilars outside of the Dosing and Frequency Requirements listed in this Policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider **must** submit those changes to the Company for a new approval based on those changes as part of the precertification process. The Company reserves the right to conduct post-payment review and audit procedures for any claims submitted for infliximab or related biosimilars.

Indication	**Dosage and Frequency**
Acute graft-versus-host disease (aGVHD) [10]	Infliximab 10 mg/kg IV weekly for a maximum of 9 doses
Anklyosing spondylitis and Nonradiographic Axial Spondyloarthritis [1]	Induction: 5 mg/kg IV at weeks 0, 2, and 6 Maintenance: 5 mg/kg IV every 6 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)
Behcet's syndrome [13]	Induction: 5 mg/kg IV at weeks 0, 2, and 6 Maintenance: 5 mg/kg IV every 6-8 weeks (up to a maximum of 10 mg/kg IV every 8 weeks)
Crohn's disease (moderate to severe) or fistulizing Crohn's disease[1, 7]	Adults: Induction: 5 mg/kg IV at weeks 0, 2, and 6 Maintenance: 5 mg/kg IV every 8 weeks. For adults who

	respond and then lose their response, consideration may be given to treatment with 10 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) Children: Induction: 5 mg/kg IV at weeks 0, 2, 6. Maintenance: 5 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) • For children who are steroid-refractory or have severe extensive or fistulizing disease, especially with hypoalbuminemia, consideration may be given for a higher induction dose of 10 mg/kg and/or decreasing the interval between infusions to 4-6 weeks.
Hidradenitis Suppurativa [11]	Induction: 5-10 mg/kg IV at weeks 0, 2, and 6 Maintenance: 5-10 mg/kg IV every 4 weeks, and with decreasing dosage as tolerated.
Toxicities Related to Immune Checkpoint Inhibitors [12]	Infliximab 5 mg/kg IV at weeks 0, 2, and 6
Inflammatory bowel disease arthritis (enteropathic arthritis)[5]	Induction: 5 mg/kg IV at weeks 0, 2, and 6 Maintenance: 5 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)
Plaque Psoriasis, severe[1, 8]	Induction: 5 mg/kg IV at weeks 0, 2, and 6 Maintenance: 5 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)
Polyarticular Juvenile Idiopathic Arthritis (JIA) [2]	Induction: 3 to 6 mg/kg IV at weeks 0, 2, and 6 Maintenance: 3 to 6 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)
Psoriatic arthritis[1]	Induction: 5 mg/kg IV at weeks 0, 2, and 6 Maintenance: 5 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)
Reactive arthritis (Reiter's disease)[6]	Induction: 3 to 5 mg/kg IV at weeks 0, 2, and 6 Maintenance: 3 to 5 mg/kg IV every 6-8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)
Rheumatoid arthritis[1]	Induction: 3 mg/kg IV at weeks 0, 2, and 6 Maintenance: 3 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)
Pyoderma gangrenosum[3]	Induction: 5 mg/kg IV at week 0. Repeat at week 2 if needed. Maintenance: 5 mg/kg IV every 4-12 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)

Sarcoidosis [4]	Induction: 3 to 5 mg/kg IV at weeks 0, 2, and 6 Maintenance: 3 to 5 mg/kg IV every 4 to 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)
Ulcerative colitis (adult and pediatric)[1, 14]	Induction: 5 mg/kg IV at weeks 0, 2, and 6 Maintenance: 5 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) • For children who are steroid-refractory or have severe extensive or fistulizing disease, especially with hypoalbuminemia, consideration may be given for a higher induction dose of 10mg/kg and/or decreasing the interval between infusions to 4-6 weeks.
Uveitis, non-infectious[9]	Induction: 3 to 10 mg/kg IV at weeks 0, 2, and 6 Maintenance: 3 to 10 mg/kg IV every 4 to 8 weeks

Duration of authorization: 12 months
Version Effective Date: 05/2026

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[2] Gerloni V, Pontikaki I, Gattinara M, et al. Efficacy of repeated intravenous infusions of an antitumor necrosis factor alpha monoclonal antibody, infliximab, in persistently active,

Field Name	Field Description
Prior Authorization Group Description	**Ketamine**
Drugs	Ketamine (Ketalar)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Depression: N/A Complex Regional Pain Syndrome (CRPS): pain management specialist
Coverage Duration	Initial: 4 weeks Continuation of therapy: 6 months

Other Criteria	**Depression**
	
	Initial Authorization:
	• Diagnosis of major depressive disorder (MDD) or treatment-resistant depression (TRD)
	• Documented trial and failure of two preferred oral antidepressants (e.g. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer OR a medical justification as to why the patient cannot use preferred alternative(s).
	Re-authorization:
	• Documentation was submitted indicating the member has clinically benefited from therapy.
	
	CRPS
	
	Initial Authorization:
	• Diagnosis of CRPS (may also be termed reflex sympathetic dystrophy, algodystrophy, causalgia, Sudeck atrophy, transient osteoporosis, and acute atrophy of bone)
	• Patient has tried and failed at least 8 weeks treatment with or continues to receive physical therapy (PT) and/or occupational therapy (OT).
	• Patient has tried and failed at least two of the following:
	  ○ NSAIDs
	  ○ Anticonvulsants (e.g. gabapentin, pregabalin)
	  ○ Antidepressants (e.g. SNRIs, TCAs)
	  ○ Bisphosphonate (in the setting of abnormal uptake on bone scan)
	Re-authorization:
	• Patient has demonstrated clinical benefit.
	
	Medical Director/clinical reviewer must override criteria when,

Revision/Review Date 11/2025	**in his/her professional judgement, the requested item is medically necessary.**

Title: Lanreotide (Somatuline® Depot)

MEDICALLY NECESSARY

Lanreotide (Somatuline® Depot) is considered medically necessary and, therefore, covered in individuals with any of the following indications when the corresponding criteria are met:

ACROMEGALY

- For the long-term treatment of individuals with acromegaly who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option.

NEUROENDOCRINE AND ADRENAL TUMORS

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

- For the treatment of unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

Neuroendocrine Tumors of the Gastrointestinal Tract (Well-Differentiated Grade 1/2), Lung and Thymus (Carcinoid Tumors)

- For the treatment of adult individuals with carcinoid syndrome to reduce the frequency of short-acting somatostatin analog rescue therapy.
- For the treatment of neuroendocrine tumors of the gastrointestinal tract, lung, and thymus (carcinoid tumors) for any of the following indications:
    - Primary treatment for symptom and/or tumor control of unresected primary gastrinoma
    - As primary therapy for symptom and/or tumor control of multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH) if chronic cough/dyspnea is not responsive to inhalers or conventional treatment

- For symptom and/or tumor control of recurrent, locoregional advanced disease and/or distant metastases* of the gastrointestinal tract as a single agent for any of the following:
    - For unresectable and a low tumor burden
    - For disease progression (if not already receiving) following resection of primary + metastases
    - For disease progression (if not already receiving) following observation for unresectable low tumor burden
    - Following resection of primary tumor if unresectable and locally symptomatic from primary tumor
    - As a single agent or in combination with alternative front-line therapy if unresectable and clinically significant tumor burden
    - As subsequent therapy at above label dosing after clinical, symptomatic, or radiographic progression (if somatostatin receptor-positive [SSTR-positive]) on standard doses (useful in certain circumstances)
- For symptom and/or tumor control of recurrent and/or locoregional unresectable bronchopulmonary/thymic disease* if SSTR-positive and/or hormonal symptoms for one of the following regimens:
    - As primary therapy
    - As subsequent therapy (as alternate primary therapy) if progression on primary therapy
- For symptom and/or tumor control of recurrent and/or distant metastatic bronchopulmonary/thymic disease* if SSTR-positive and/or hormonal symptoms for one of the following regimens:
    - As primary therapy
    - As subsequent therapy (as alternate primary therapy) if progression on primary therapy
- For symptom and/or tumor control of recurrent and/or distant metastatic bronchopulmonary/thymic disease* if SSTR-positive and/or hormonal symptoms for one of the following regimens:
    - As primary therapy (National Comprehensive Cancer Network [NCCN] preferred if clinically significant tumor burden and low grade [typical carcinoid], evidence of disease progression, intermediate grade [atypical carcinoid], or symptomatic)

- As subsequent therapy (as alternate primary therapy) if progression on primary therapy if clinically significant tumor burden and low grade (typical carcinoid), evidence of disease progression, intermediate grade (atypical carcinoid), or symptomatic (NCCN preferred)

- Treatment of carcinoid syndrome for any of the following regimens:
  - As a single agent
  - In combination with telotristat for persistent diarrhea due to poorly controlled carcinoid syndrome
  - In combination with other systemic therapy options (based on disease site) with or without telotristat for persistent symptoms (i.e., flushing, diarrhea) due to poorly controlled carcinoid syndrome

Neuroendocrine and Adrenal Tumors - Well-Differentiated Grade 3 Neuroendocrine Tumors

- For the treatment and/or tumor control of SSTR-positive (if SSTR-positive and/or hormonal symptoms) for unresectable locally advanced/metastatic disease with favorable biology (e.g., relatively low Ki-67 [<55%], slow growing, positive SSR-based PET imaging) at standard dose

Tumors of the Pancreas (Well-Differentiated Grade 1/2)

- Management of symptoms and/or tumor control of locoregional disease with any of the following indications:
  - Gastrinoma (usually duodenal or head of the pancreas)
  - Glucagonoma (usually tail)
  - VIPoma

- As NCCN-preferred regimen for symptom and/or tumor control* in individuals** with recurrent or locoregional advanced disease and/or distant metastatic disease if SSTR-positive with any of the following indications:
  - As a single agent for asymptomatic, low tumor burden and stable disease
  - As a single agent for symptomatic, clinically significant tumor burden, or clinically significant progression (if not already receiving)

    - In combination with alternative front-line therapy for symptomatic, clinically significant tumor burden, or clinically significant progression
- For symptom and/or tumor control as subsequent therapy at above label dosing after clinical, symptomatic or radiographic progression on standard doses (if SSTR-positive)

Pheochromocytoma/Paraganglioma

- As primary treatment for secreting tumors for hormone excess and symptom control of locally unresectable disease or distant metastases (if SSTR-positive)

NCCN note: *If clinically significant disease progression, treatment with lanreotide should be discontinued for nonfunctional tumors and continued in individuals with functional tumors and may be used in combination with any of the subsequent options.

NCCN note: ** For individuals with insulinoma, lanreotide should be used only if SSTR-based imaging is positive.

Duration of authorization: 12 months

Version Effective Date: 10/01/2024

Attachment A: Lanreotide (Somatuline® Depot)
Description: ICD-10 CODES AND NARRATIVES

Policy Attachment

Attachment to Policy # 08.01.40g

Attachment: A

Policy #: 08.01.40g

Description: ICD-10 CODES AND NARRATIVES

Title: Lanreotide (Somatuline® Depot)

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

ICD-10 CODES AND NARRATIVES

C25.0 Malignant neoplasm of head of pancreas
C25.1 Malignant neoplasm of body of pancreas
C25.2 Malignant neoplasm of tail of pancreas
C25.3 Malignant neoplasm of body of pancreatic duct
C25.4 Malignant neoplasm of endocrine pancreas
C25.7 Malignant neoplasm of other parts of pancreas
C25.8 Malignant neoplasm of overlapping sites pancreas
C25.9 Malignant neoplasm of pancreas, unspecified
C26.0 Malignant neoplasm of intestinal tract, part unspecified
C26.9 Malignant neoplasm of ill-defined sites within the digestives system
C7A.00 Malignant carcinoid tumor of unspecified site
C7A.010 Malignant carcinoid tumor of the duodenum
C7A.011 Malignant carcinoid tumor of the jejunum
C7A.012 Malignant carcinoid tumor of the ileum
C7A.019 Malignant carcinoid tumor of the small intestine, unspecified portion
C7A.020 Malignant carcinoid tumor of the appendix
C7A.021 Malignant carcinoid tumor of the cecum
C7A.022 Malignant carcinoid tumor of the ascending colon
C7A.023 Malignant carcinoid tumor of the transverse colon
C7A.024 Malignant carcinoid tumor of the descending colon
C7A.025 Malignant carcinoid tumor of the sigmoid colon
C7A.026 Malignant carcinoid tumor of the rectum
C7A.029 Malignant carcinoid tumor of the large intestine, unspecified portion
C7A.090 Malignant carcinoid tumor of the bronchus and lung
C7A.091 Malignant carcinoid tumor of the thymus
C7A.092 Malignant carcinoid tumor of the stomach
C7A.094 Malignant carcinoid tumor of the foregut, unspecified

C7A.095 Malignant carcinoid tumor of the midgut, unspecified
C7A.096 Malignant carcinoid tumor of the hindgut, unspecified
C7A.098 Malignant carcinoid tumors of other sites
C7A.1 Malignant poorly differentiated neuroendocrine tumors
C7A.8 Other malignant neuroendocrine tumors
C7B.00 Secondary carcinoid tumors, unspecified site
C7B.01 Secondary carcinoid tumors of distant lymph nodes
C7B.02 Secondary carcinoid tumors of liver
C7B.03 Secondary carcinoid tumors of bone
C7B.04 Secondary carcinoid tumors of peritoneum
C7B.09 Secondary carcinoid tumors of other sites
C7B.8 Other secondary neuroendocrine tumors
C74.10 Malignant neoplasm of medulla of unspecified adrenal gland
C74.11 Malignant neoplasm of medulla of right adrenal gland
C74.12 Malignant neoplasm of medulla of left adrenal gland

C74.90 Malignant neoplasm of unspecified part of unspecified adrenal gland

C74.91 Malignant neoplasm of unspecified part of right adrenal gland

C74.92 Malignant neoplasm of unspecified part of left adrenal gland

C75.5 Malignant neoplasm of aortic body and other paraganglia
D13.7 Benign neoplasm of endocrine pancreas

D37.8 Neoplasm of uncertain behavior of other specified digestive organs
D3A.00 Benign carcinoid tumor of unspecified site
D3A.010 Benign carcinoid tumor of the duodenum
D3A.011 Benign carcinoid tumor of the jejunum
D3A.012 Benign carcinoid tumor of the ileum
D3A.019 Benign carcinoid tumor of the small intestine, unspecified portion
D3A.020 Benign carcinoid tumor of the appendix
D3A.021 Benign carcinoid tumor of the cecum
D3A.022 Benign carcinoid tumor of the ascending colon
D3A.023 Benign carcinoid tumor of the transverse colon
D3A.024 Benign carcinoid tumor of the descending colon
D3A.025 Benign carcinoid tumor of the sigmoid colon
D3A.026 Benign carcinoid tumor of the rectum
D3A.029 Benign carcinoid tumor of the large intestine, unspecified portion
D3A.090 Benign carcinoid tumor of the bronchus and lung
D3A.091 Benign carcinoid tumor of the thymus
D3A.092 Benign carcinoid tumor of the stomach
D3A.094 Benign carcinoid tumor of the foregut, unspecified

D3A.095 Benign carcinoid tumor of the midgut, unspecified
D3A.096 Benign carcinoid tumor of the hindgut, unspecified
D3A.098 Benign carcinoid tumors of other sites
D3A.8 Other benign neuroendocrine tumors
D49.0 Neoplasm of unspecified behavior of digestive system

E16.1 Other hypoglycemia
E16.3 Increased secretion of glucagon
E16.4 Increased secretion of gastrin
E16.8 Other specified disorders of pancreatic internal secretion
E22.0 Acromegaly and pituitary gigantism

E22.2 Syndrome of inappropriate secretion of antidiuretic hormone
E34.00 Carcinoid syndrome, unspecified

E34.01 Carcinoid heart syndrome

E34.09 Other carcinoid syndrome

Version Effective Date: 10/01/2024

Version Issued Date: 10/01/2024

Version Reissued Date: N/A

Title: Lifileucel (Amtagvi™)

MEDICALLY NECESSARY

Lifileucel (Amtagvi) as a component of tumor-infiltrating lymphocyte (TIL) therapy is considered medically necessary and, therefore, covered in adult individuals with unresectable or metastatic melanoma* and **all** of the following:

- as second-line or subsequent systemic therapy** as National Comprehensive Cancer Network (NCCN)-preferred therapy after progression on **both**
    - PD-1 blocking antibody (e.g., Keytruda, Opdivo) and
    - BRAF inhibitor (e.g., Braftovi, Tafinlar, Zelboraf) with or without a MEK inhibitor (e.g., Cotellic, Mekinist, Mektovi) if BRAF V600 mutation positive.
- Eastern Cooperative Oncology Group (ECOG) performance status score of PS 0 or 1
- The individual has at least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter, postresection, to generate cell therapy
- The individual has adequate and stable kidney, pulmonary and cardiac function
- The individual does not have clinically significant active systemic infection
- The individual does not have uncontrolled brain metastasis
- The individual does not have uveal or ocular melanoma
- The individual does not have a history of prior cell transfer therapy

Note: one-time lifileucel TIL cell therapy.

*Metastatic disease includes stage III unresectable/borderline resectable disease with clinically positive node(s) or clinical satellite/in-transit metastases, or as well as unresectable/borderline resectable local satellite/in-transit recurrence, unresectable nodal recurrence, and widely disseminated distant metastatic disease.
**Systemic therapy is preferred for unresectable or widely disseminated distant metastatic disease.

MANDATES

PENNSYLVANIA MEMBERS

In accordance with the Commonwealth of Pennsylvania's Act 6 of 2020 or Fair Access to Cancer Treatment Act, for members who are enrolled in Pennsylvania commercial products who have Stage 4, advanced metastatic cancer, refer to the Medical Policy titled "Coverage of Anticancer Prescription Oral and Injectable Drugs and Biologics and Supportive Agents" (08.01.08) for additional information regarding the applicable coverage of drugs and biologics.

EXPERIMENTAL/INVESTIGATIONAL

All other uses for lifileucel (Amtagvi) not identified in this policy are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

NOT ELIGIBLE FOR SEPARATE REIMBURSMENT

The harvesting and preparation of blood-derived T lymphocytes and the receipt and preparation of T cells are not eligible for separate reimbursement from the TIL administration.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Duration of authorization: 1 month

Version Effective Date: 10/21/2024

Title: Lovotibeglogene autotemcel (Lyfgenia®)

MEDICALLY NECESSARY

Lyfgenia® (lovotibeglogene autotemcel) is considered medically necessary and, therefore, covered for the treatment of severe sickle cell disease (SCD) in individuals with age ≥ 12 years when ALL of the associated criteria for them are met:

- Individual has diagnosis of severe SCD with one of the following genotypes as confirmed by genetic testing results [(a or b):

a. βS/βS;

b. βS/β0;

- Documentation that the individual is a candidate for an allogeneic HSCT, but ineligible due to absence of an appropriate donor (i.e., individual does not have a Human Leukocyte Antigen (HLA)-matched donor; or individual has an HLA-matched donor, but the potential donor is not able or is not willing to donate);
- Individual has not received a prior allogenic hematopoietic stem cell transplant;

- Individual is eligible to receive an autologous hematopoietic stem cell transplant;
- Individual has had been treated with at least ONE pharmacologic treatment for sickle cell disease (e.g., pharmacologic treatment for sickle cell disease include hydroxyurea, Lglutamine, Adakveo (crizanlizumab-tmca intravenous infusion), and Oxbryta (voxelotor tablets and tablets for oral suspension));
- While receiving appropriate standard treatment for sickle cell disease, individual had at least four severe vaso-occlusive crises or events (VOCs/VOEs) in the previous two years, which can be defined by one or more of the following (i, ii, iii, iv, or v):

i. An episode of acute pain that resulted in a visit to a medical facility which required administration of at least ONE of the following (a or b):

a) Intravenous opioid; OR

b) Intravenous nonsteroidal anti-inflammatory drug;

ii. Acute chest syndrome (acute chest syndrome is defined by the presence of a new pulmonary infiltrate associated with pneumonia-like symptoms (e.g., chest pain, fever [> 99.5°F], tachypnea, wheezing or cough, or findings upon lung auscultation);

iii. Acute hepatic sequestration (acute hepatic sequestration is defined by a sudden increase in liver size associated with pain in the right upper quadrant, abnormal results of liver function test not due to biliary tract disease, and the reduction of hemoglobin concentration by ≥ 2 g/dL below the baseline value);

iv. Acute splenic sequestration (acute splenic sequestration is defined by an enlarged spleen, left upper quadrant pain, and an acute decrease in hemoglobin concentration of ≥ 2 g/dL below the baseline value);

v. Acute priapism lasting > 2 hours and requiring a visit to a medical facility;

- The gene therapy is prescribed by a hematologist or a stem cell transplant physician; AND
- Individual has not received any gene therapy and/or is not under consideration for treatment for another gene therapy for sickle cell disease.

EXPERIMENTAL/INVESTIGATIONAL

All other uses, including when the above criteria are not met, for Lyfgenia® (lovotibeglogene autotemcel) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Duration of authorization: 12 months

Version Effective Date: 2/2026

Title: Lumasiran (Oxlumo®)

MEDICALLY NECESSARY

INITIAL APPROVAL

Lumasiran (Oxlumo®) is considered medically necessary and, therefore, covered for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult individuals when ALL of the following criteria are met:

- Diagnosis of PH1 confirmed by identification of biallelic pathogenic variants in alanine:glyoxylate aminotransferase (*AGT or AGXT*) gene OR liver biopsy demonstrating AGT deficiency.
- Presence of one of the following, which are associated with clinical presentation of PH1
    - Elevated urine oxalate excretion (body surface area–normalized daily urine oxalate excretion output ≥0.7 mmol/1.73 m^2)
    - Elevated plasma oxalate concentration >20 µmol/L or >1.76 mg/L
    - Urine oxalate excretion:creatinine ratio above age-specific upper limit of normal
- Individual has not received a liver transplant.
- Prescribed by or in consultation with a nephrologist, urologist, geneticist, or any healthcare provider with expertise in treating PH1.

CONTINUATION OF TREATMENT

Continuation of lumasiran (Oxlumo®) is considered medically necessary and, therefore, covered when ALL of the following requirements are met:

- Individual continues to meet the initial treatment criteria cited above.
- Documented evidence to support clinically meaningful response to therapy from pretreatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate:creatinine ratio, decreased plasma oxalate concentrations, improvement, stabilization or slowed worsening of nephrocalcinosis, renal stone events, renal impairment or systemic calcinosis).
- Does not exceed US Food and Drug Administration–approved maintenance dose

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Mirikizumab-mrkz (Omvoh™) for Intravenous Use

MEDICALLY NECESSARY

Mirikizumab-mrkz (Omvoh™) administered via an intravenous (IV) route, is considered medically necessary and, therefore, covered for the treatment of moderately to severely active ulcerative colitis (UC) in adults when **ALL** the following are met:

- Individual has a diagnosis of moderately to severely active ulcerative colitis, as assessed by a validated rating index/scale (e.g., modified Mayo score [MMS]), or a diagnosis of moderately to severely active Crohn's disease
- For UC diagnosis, individual has demonstrated an inadequate response to, loss of response, or intolerance to **BOTH** of the following:
    - One or more conventional therapies (e.g., corticosteroids, aminosalicylates, immunomodulators) for UC*
    - Two advanced therapies (biologic/Janus kinase [JAK] inhibitor therapy) for UC*
- Individual has no prior exposure to anti-interleukin (anti-IL)-12p40 antibodies (e.g., ustekinumab) or anti-IL-23p19 antibodies (e.g., risankizumab, brazikumab, guselkumab, tildrakizumab)
- Mirikizumab-mrkz (Omvoh) is prescribed by, or in consultation with, a licensed gastroenterology professional provider.

*See Description section for specific examples.

EXPERIMENTAL/INVESTIGATIONAL

All other uses for mirikizumab-mrkz (Omvoh) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These

medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Mogamulizumab-kpkc (Poteligeo®)

MEDICALLY NECESSARY

ADULT T-CELL LEUKEMIA/LYMPHOMA

Mogamulizumab-kpkc (Poteligeo®) injection is considered medically necessary and, therefore, covered for individuals with a diagnosis of adult T-cell leukemia/lymphoma (ATTL), as a second-line or subsequent therapy as a single agent for nonresponders to first-line therapy for acute or lymphoma* subtypes (National Comprehensive Cancer Network [NCCN]-preferred treatment)

MYCOSIS FUNGOIDES OR SÉZARY SYNDROME

Mogamulizumab-kpkc (Poteligeo®) injection is considered medically necessary and, therefore, covered as monotherapy for individuals 18 years of age or older with diagnosis of relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy, when any of the following criteria are met:

- The individual is receiving primary systemic therapy for one of the following stages of the disease:
    - Stage IB-IIA MF, in combination with skin-directed therapy in select cases** (NCCN-preferred treatment)
    - Stage IIB MF with limited tumor lesions, with or without local radiation therapy and with or without skin-directed therapy (NCCN-preferred treatment)
    - Stage IIB MF with generalized tumor lesions, in combination with skin-directed therapy (NCCN-preferred treatment)
    - Stage III MF in combination with skin-directed therapy (NCCN-preferred treatment)
    - Stage IVA1 or IVA2 SS, in combination with skin-directed therapy (NCCN-preferred treatment)
    - Stage IVA2 non-SS or stage IVB visceral disease (solid organ), with or without radiation therapy for local control
- The individual is receiving subsequent systemic therapy for one of the following stages of the disease:

- Stage IA MF that is refractory to multiple previous therapies, in combination with skin-directed therapy** (NCCN-preferred treatment)

- Stage IB-IIA MF that is relapsed with a lower skin disease burden (e.g., predominantly patch disease), in combination with skin-directed therapy in selected cases** (NCCN-preferred treatment)
- Stage IB-IIA MF with a higher skin disease burden (e.g., predominantly plaque disease) that is relapsed or persistent with T1-T2 disease, in combination with skin-directed therapy in selected cases** (NCCN-preferred treatment)
- Stage IB-IIA MF that is refractory to multiple previous therapies, in combination with skin-directed therapy (NCCN-preferred treatment)
- Stage IIB MF that is relapsed with T1-2 limited tumor lesions, in combination with skin-directed therapy in selected cases** (NCCN-preferred treatment)
- Stage IIB MF with T3 limited tumor lesions that is relapsed with or without local radiation therapy and with or without skin-directed therapy (NCCN-preferred treatment)
- Stage IIB MF that is persistent with T1-3 limited tumor lesions with or without local radiation therapy and with or without skin-directed therapy (NCCN-preferred treatment)

- Stage IIB MF with limited tumor lesions that is refractory to multiple previous therapies, in combination with skin-directed therapy (NCCN-preferred treatment)
- Stage IIB MF that is relapsed with T1-2 generalized tumor lesions, in combination with skin-directed therapy in selected cases** (NCCN-preferred treatment)
- Stage IIB MF that is persistent with T1-3 generalized tumor lesions, in combination with skin-directed therapy (NCCN-preferred treatment)
- Stage IIB MF with generalized tumor lesions refractory to multiple previous therapies
- Stage IIB MF with T3 generalized tumor lesions that is relapsed in combination with or without skin-directed therapy (NCCN-preferred treatment)
- Stage III MF that is relapsed or persistent in combination with skin-directed therapy (NCCN-preferred treatment)

- Stage III MF that is refractory to multiple previous therapies in combination with skin-directed therapies
- Stage IVA1or IVA2 SS that is relapsed or persistent in combination with skin-directed therapy ([NCCN]-preferred treatment)
- Stage IVA2 that is relapsed or persistent non-SS or stage IVB visceral disease (solid organ), with or without radiation therapy for local control

NCCN note: *The Lymphoma Study Group of the Japan Clinical Oncology Group (JCOG) has classified ATLL into four subtypes (smoldering, chronic, acute, or lymphoma based on laboratory evaluations [e.g., serum LDH, calcemia, lymphocytosis] and clinical features [e.g., lymphadenopathy, hepatosplenomegaly, skin involvement]).

NCCN note: **Systemic therapies should be considered for individuals with extensive skin involvement, higher skin disease burden, predominantly plaque disease, blood involvement, and/or inadequate response to skin-directed therapy.

CONTINUATION THERAPY
Mogamulizumab-kpkc (Poteligeo) is considered medically necessary and, therefore, covered for continuation therapy until disease progression, drug intolerance, unacceptable toxicity, or any other criteria for discontinuation of the therapy.

MANDATES

PENNSYLVANIA MEMBERS

In accordance with the Commonwealth of Pennsylvania's Act 6 of 2020 or Fair Access to Cancer Treatment Act, for members who are enrolled in Pennsylvania commercial products who have Stage 4, advanced metastatic cancer, refer to the Medical Policy titled "Coverage of Anticancer Prescription Oral and Injectable Drugs and Biologics and Supportive Agents" (08.01.08) for additional information regarding the applicable coverage of drugs and biologics.

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Version Effective Date: 03/05/2025

Title: Natalizumab (Tysabri®) and Related Biosimilars

MEDICALLY NECESSARY

MULTIPLE SCLEROSIS
Natalizumab (Tysabri®) and related biosimilars are considered medically necessary and, therefore, covered as monotherapy for the treatment of adults with relapsing forms of multiple sclerosis (MS) (to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease) when **ONE** of the following criteria is met:

- The individual has documentation of highly active (aggressive) relapsing MS defined as, but not limited to, accumulating disability, multiple new or enlarging of lesions of brain and/or spinal cord that developed in the first year of illness
- The individual has had an inadequate response to, or is unable to tolerate, alternate MS therapies (e.g., interferon beta-1a [Avonex®, Rebif®], interferon beta-1b [Betaseron®], glatiramer acetate [Copaxone®])

CROHN'S DISEASE
Natalizumab (Tysabri) and related biosimilars are considered medically necessary and, therefore, covered for the treatment of adults with moderately to severely active Crohn's disease (CD), who have evidence of inflammation, to induce and maintain clinical response and remission when **ALL** of the following criteria are met:

- The individual has had an inadequate response to, or is unable to tolerate, conventional CD therapies and inhibitors of tumor necrosis factor-alpha (TNF-α)
- Natalizumab (Tysabri) and related biosimilars will not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) or TNF-α inhibitors (e.g., adalimumab, infliximab)

ANTI-JCV ANTIBODY
Measurement of anti-JCV antibodies (John Cunningham Virus) with ELISA (enzyme-linked immunosorbent assay) is considered medically necessary and, therefore, covered when tested prior to initiation of natalizumab (Tysabri) and related biosimilars treatment and every 6 months thereafter, to assess the risk of developing progressive multifocal leukoencephalopathy (PML).

ANTI-NATALIZUMAB ANTIBODIES
Measurement of anti-natalizumab antibodies is considered medically necessary and, therefore, covered in an individual receiving treatment with natalizumab (Tysabri) and related biosimilars when persistent anti-natalizumab antibodies are suspected to have caused a documented hypersensitivity or when there has been an extended dose interruption of natalizumab (Tysabri) and related biosimilars therapy. This test should be repeated 3 months after an initial positive result is detected to confirm that the antibodies are persistent.

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Nutritional Formulas, Enteral Nutrition, Medical Foods, Low-Protein Modified Food Products, and Donated Breast Milk

MEDICALLY NECESSARY

NUTRITIONAL FORMULAS AND ENTERAL NUTRITION
Administration Through a Tube

Commercially available nutritional formulas (including enteral nutrition) and associated enteral supplies (including pump, tubing, feeding supply kits) prescribed by a professional provider are considered medically necessary and, therefore, covered for individuals of all ages when **all** of the following criteria **AND** the subsequent mandate criteria are met:

- The commercially available nutritional formula requires administration via a tube (e.g., percutaneous endoscopic gastrostomy [PEG] tube, jejunostomy tube [J-tube], percutaneous endoscopic jejunostomy [PEJ], nasogastric [NG] tube) into the alimentary canal.
- The tube feeding does not have to be the sole source of nutrition (i.e., more than 75% of estimated basal caloric requirements).
- Examples of nutritional formulas and enteral nutrition that can be administered through a tube include, but are not limited to, Boost, EleCare Infant or Jr., Glucerna, Isosource, Jevity, Nutren, Osmolite, PediaSure, Peptamen, Tolerex, Vivonex.

For Pennsylvania infant and child members, see Attachment A for PA Mandate Information.
For New Jersey members 12 months and under, see Attachment B for NJ Mandate Information.
For information regarding caloric requirements, see Attachment C.

Administration Orally

<u>Infants and Children</u>
Commercially available nutritional formulas prescribed by a professional provider are considered medically necessary and, therefore, covered for infants and children who require oral administration of an elemental formula (e.g., EleCare Infant or Jr., Neocate Splash, PurAmino, Neocate Junior or Infant, Tolerex, Vivonex) as the sole source of nutrition (i.e., the formula provides more than 75% of estimated basal caloric requirements) and who meet **one or more** of the following criteria **AND** meet the subsequent Mandate criteria:

- The individual suffers from severe systemic protein hypersensitivity (e.g., IgE-mediated: eosinophilic esophagitis, eosinophilic gastritis, eosinophilic gastroenteritis; non–IgE-mediated: food protein–induced entities such as enterocolitis) that is refractory to dietary and other treatments. Infants younger than 1 year of age must be shown to be refractory to treatment for at least 2 weeks with standard milk or soy protein formulas (e.g., Enfamil A.R., Similac with Iron, Similac for Diarrhea, Enfamil Prosobee), and refractory to treatment for at least 2 weeks with nonstandard, extensively hydrolyzed formulas (e.g., Nutramigen, Pregestimil, Similac Alimentum).
- The individual has a disorder(s) of gross anatomy impeding or obstructing passage of nutrition through the alimentary canal (e.g., stricture, tumor, blind pouches).

For Pennsylvania infant and child members, see Attachment A for PA Mandate Information.

NOTE: Members enrolled in a Pennsylvania Product are **not** required to meet the Company's definition of sole source of nutrition (i.e., the formula provides more than 75% of estimated basal caloric requirements); therefore, an estimated basal caloric requirement is not required.

For New Jersey members 12 months and under, see Attachment B for NJ Mandate Information. For information regarding caloric requirements, see Attachment C.

Adults

Commercially available nutritional
formulas (e.g., Boost, Ensure, Glucerna, Jevity, Osmolite) prescribed by a professional provider are considered medically necessary and, therefore, covered for adults who require oral administration of nutritional formulas as the sole source of nutrition (i.e., the formula provides more than 75% of estimated basal caloric requirements) when the individual has a disorder(s) of gross anatomy impeding or obstructing the passage of nutrition through the alimentary canal (e.g., stricture, tumor, blind pouches).

For information regarding caloric requirements, see Attachment C.

MEDICAL FOODS FOR INBORN ERRORS OF METABOLISM ADMINISTERED ORALLY OR THROUGH A TUBE

Medical foods prescribed by a professional provider and administered orally or via a tube into the alimentary canal for individuals diagnosed with genetic (inherited) inborn errors of metabolism (IEM), such as phenylketonuria (PKU), homocystinuria, branched-chain ketonuria, galactosemia, and maple syrup urine disease, are covered for individuals of all ages who need administration of a formula that is manufactured for individuals with IEMs.

- Medical foods are **not** required to meet the Company's definition of sole source of nutrition (i.e., the formula provides more than 75% of estimated basal caloric

requirements); therefore, an estimated basal caloric requirement is not required for IEMs.

- Examples of medical foods for individuals diagnosed with IEM include, but are not limited to, BCAD 1 or 2, OA 1 or 2, PFD 2 or Toddler, PhenylAde, Phenyl-Free 1 or 2 or 2HP, Ketonex 1 or 2.

For Pennsylvania members, see Attachment A for PA Mandate Information.
For New Jersey members, see Attachment B for NJ Mandate Information.
For information regarding caloric requirements, see Attachment C.

LOW-PROTEIN MODIFIED FOODS FOR INBORN ERRORS OF METABOLISM

New Jersey Products

Low-protein modified food products prescribed by a professional provider are covered by the Company in accordance with the state mandates for individuals enrolled in a New Jersey product subject to New Jersey's insurance law who are diagnosed with an inherited errors of metabolism, and the treatment is determined to be medically necessary by the individual's physician.

For New Jersey members, see Attachment B for NJ Mandate Information.

Pennsylvania Products

Low-protein modified food products are not covered by the Company for individuals enrolled in Pennsylvania products for IEM because they do not meet the Company's definition of medical foods or nutritional formulas. Therefore, they are not eligible for reimbursement consideration.

For Pennsylvania members, see Attachment A for PA Mandate Information.

IMMOBILIZED LIPASE CARTRIDGE (E.G., RELIZORB)

Initial Therapy

Immobilized lipase cartridge (e.g., Relizorb), up to six cartridges per day, is considered medically necessary and, therefore, covered for individuals 2 years of age and older when all of the

following criteria are met:

- The individual has a documented diagnosis of cystic fibrosis with exocrine pancreatic insufficiency
- The individual has continued malabsorption of fats (i.e., weight loss or inadequate weight gain) from enteral formula despite optimization of pancreatic enzyme replacement therapy (PERT)

Continuation Therapy

Immobilized lipase cartridge (e.g., Relizorb) is considered medically necessary and, therefore, covered for continuation therapy when the individual with cystic fibrosis and exocrine pancreatic insufficiencymeets both of the following:

- There is documentation of a positive clinical response or stabilization due to the cartridge use (e.g., weight gain, BMI increase to—or maintained at—50th percentile, or decreased symptoms of malabsorption, such as diarrhea)
- The individual is not using more than six cartridges per day, per product labeling

NOT COVERED

Nutritional formulas, enteral nutrition, or medical foods not prescribed by a healthcare provider are not covered by the Company because they are a benefit contract exclusion. Therefore, they are not eligible for reimbursement consideration.

Infant, child, or adult nutritional formulas or enteral nutrition that do not meet the Company's coverage criteria are not covered by the Company, and are, therefore, not eligible for reimbursement consideration. Examples include the following:

- Extensively hydrolyzed formulas (e.g., Nestle Extensive HA, Nutramigen, Pregestimil, Similac Alimentum)
- Oral polymeric formulas (e.g., Boost, Enfamil EnfaCare, Ensure, NeoSure, PediaSure, Scandishake) for infants and children

- Oral nutritional formulas and enteral nutrition for individuals with a diagnosis of malnutrition due to anorexia or failure to thrive
- Oral organic formulas (e.g., Kate Farms Organic formula, Similac Organic formula)

Banked breast milk is not covered by the Company, and is therefore not eligible for reimbursement consideration. For members enrolled in New Jersey Products, donated banked breast milk may be covered through a New Jersey Mandate. Individual benefits must be verified.

Elemental semisolid foods (e.g., Neocate Nutra) are not covered by the Company, and are therefore not eligible for reimbursement consideration.

Products that are used to replace fluids and electrolytes (e.g., Electrolyte Gastro, Pedialyte), for adults and children, are not covered by the Company, and are therefore not eligible for reimbursement consideration.

Medical foods for non-IEM (e.g., Encala) are not covered by the Company because they are a benefit contract exclusion. Therefore, they are not eligible for reimbursement consideration.

Oral additives (e.g., Duocal, fiber, probiotics, supplements [e.g., PKU Easy Microtabs] or vitamins) and food thickeners (e.g., Thick-It, Resource ThickenUp) for adults and children, are not covered by the Company, and are therefore not eligible for reimbursement consideration.

- Most prescribed enteral formulas are nutritionally complete (i.e., they contain all vital nutrients, including vitamins and fiber). Therefore, additives and food thickeners are not eligible for separate reimbursement.
    - Nutritional formulas that are incomplete are described as such because they consist of specific nutrients to meet the nutritional needs of individuals with IEM.

Supplies associated with the oral administration of formula (e.g., bottles, nipples) are not covered by the Company, and are therefore not eligible for reimbursement consideration.

EXPERIMENTAL/INVESTIGATIONAL

All other uses for nutritional formulas, enteral nutrition, medical foods, low-protein modified food products, and immobilized lipase cartridge (e.g., Relizorb) are considered experimental/investigational and, therefore, not covered because their safety and/or effectiveness cannot be established by review of the available published peer-reviewed literature.

REQUIRED DOCUMENTATION

The Company may conduct reviews and audits of services to our members regardless of the participation status of the provider. Medical record documentation must be maintained on file to reflect the medical necessity of the care and services provided. These medical records may include but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

STANDARD ORDER
Before submitting a claim to the Company, the supplier must have on file a timely, appropriate, and complete order for each item billed that is signed and dated by the professional provider who is treating the member. Requesting a provider to sign a retrospective order at the time of an audit or after an audit for submission as an original order, reorder, or updated order will not satisfy the requirement to maintain a timely professional provider order on file.

PROOF OF DELIVERY
Medical record documentation must include a contemporaneously prepared delivery confirmation or member's receipt of supplies and equipment. The medical record documentation must include a copy of delivery confirmation if delivered by a commercial carrier and a signed copy of delivery confirmation by member/caregiver if delivered by the durable medical equipment (DME) supplier/provider. All documentation is to be prepared contemporaneous with delivery and be available to the Company upon request.

ASSOCIATED SUPPLIES (WHEN APPLICABLE)
The DME supplier must monitor the quantity of accessories and supplies an individual is actually using. Contacting the individual regarding replenishment of supplies should not be done earlier than approximately 30 days prior to the delivery/shipping date. Dated documentation of this contact with the individual is required in the individual's medical record. Delivery of the supplies should not be done earlier than approximately 10 days before the individual would exhaust their on-hand supply.

If required documentation is not available on file to support a claim at the time of an audit or

record request, the DME supplier may be required to reimburse the Company for overpayments.

The maximum number of supplies that can be dispensed at one time is no more than a 1-month supply (maximum 31-day supply). Supply allowance HCPCS codes (B4034, B4035, B4036, and B4148) are daily allowances that are considered all-inclusive and therefore refill requirements are not applicable to these HCPCS codes.

Duration of authorization: 12 months

Version Effective Date: 11/2025

Attachment A: Nutritional Formulas, Enteral Nutrition, Medical Foods, Low-Protein Modified Food Products, and Donated Breast Milk
Description: PA Mandates
Attachment B: Nutritional Formulas, Enteral Nutrition, Medical Foods, Low-Protein Modified Food Products, and Donated Breast Milk
Description: NJ Mandates
Attachment C: Nutritional Formulas, Enteral Nutrition, Medical Foods, Low-Protein Modified Food Products, and Donated Breast Milk
Description: Caloric Requirements

Policy Attachment

Attachment to Policy # 08.00.18q

Attachment: A

Policy #: 08.00.18q

Description: PA Mandates

Title: Nutritional Formulas, Enteral Nutrition, Medical Foods, Low-Protein Modified Food Products, and Donated Breast Milk

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COMMONWEALTH OF PENNSYLVANIA MANDATE

Coverage is subject to the terms, conditions, and limitations of the member's contract. State mandates do not automatically apply to self-funded groups, but may be included or excluded at the option of the group; therefore, individual group benefits must be verified.

For members enrolled in a Pennsylvania product, The Medical Foods Insurance Coverage Act makes provision of insurance coverage for the following:

NUTRITIONAL FORMULAS AND ENTERAL NUTRITION

Pennsylvania mandates require coverage of orally or enterally administered amino acid-based elemental medical formulas (i.e., formula made of 100% free amino acids as the protein source) when ordered by a physician as medically necessary for infants and children with food protein allergies, food protein-induced enterocolitis syndrome, eosinophilic disorders and short bowel syndrome.

NOTE: Members described above are not required to meet the Company's definition of sole source of nutrition (i.e., the formula provides more than 75 percent of estimated basal caloric requirements); therefore, an estimated basal caloric requirement is not required.

MEDICAL FOODS FOR INBORN ERRORS OF METABOLISM ADMINISTERED ORALLY OR THROUGH A TUBE

Prescription medical foods (formulas) administered orally or via a tube into the alimentary canal for individuals diagnosed with a rare genetic (inherited) inborn errors of metabolism (IEM), such as phenylketonuria (PKU), homocystinuria, branched-chain ketonuria, and galactosemia are covered for individuals of all ages who need administration of a formula that is manufactured for the therapeutic treatment and dietary management of individuals with IEMs and is administered under the direction of a physician.

- Medical foods are not required to meet the Company's definition of sole source of nutrition (i.e., the formula provides more than 75 percent of estimated basal caloric requirements); therefore, an estimated basal caloric requirement is not required for IEMs.
- Medical foods are exempt from Deductible requirements.

LOW-PROTEIN MODIFIED FOOD PRODUCTS FOR INBORN ERRORS OF METABOLISM

Pennsylvania Mandate does not require coverage for low-protein modified food products such as breads, pasta, pastry shells, and rice pizza shells that can be purchased commercially without a prescription and are used in the dietary management of rare hereditary genetic metabolic disorders such as PKU, branched chain-ketonuria, galactosemia, and homocystinuria.

REFERENCES

Laws of PA. 1492. Act 1996-191. HB 1532. Approved 12/20/1996. Available at: http://www.palrb.us/pamphletlaws/19001999/1996/0/act/0191.pdf or http://www.legis.state.pa.us/cfdocs/billinfo/billinfo.cfm?syear=1995&sind=0&body=H&type=B&bn=1532.

Amended Act of Oct. 22, 2014, P.L. 2564, No. 158. Cl. 40. PA HB 1436. Available at: http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2014&sessInd=0&act=158.

Version Effective Date: 11/2025

Policy Attachment

Attachment to Policy # 08.00.18q

Attachment: B

Policy #: 08.00.18q

Description: NJ Mandates

Title: Nutritional Formulas, Enteral Nutrition, Medical Foods, Low-Protein Modified Food Products, and Donated Breast Milk

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NEW JERSEY STATE MANDATES

Coverage is subject to the terms, conditions, and limitations of the member's contract. State mandates do not automatically apply to self-funded groups, but may be included or excluded at the option of the group; therefore, individual group benefits must be verified.

NEW JERSEY SPECIALTY INFANT FORMULA PROGRAM

For members enrolled in a New Jersey product, Coverage of Certain Infant Formulas Act 2001-2002, P.L. 2001, Ch 361, makes provision of insurance coverage for specialized nonstandard infant formulas, when the covered infant's physician has diagnosed the infant as having multiple food protein intolerance and has determined such formula to be medically necessary, and when the covered infant has not been responsive to trials of standard non-cow milk-based formulas, including soybean and goat milk.

In accordance with NJ Statute, P.L. 2001, c.361, specialized nonstandard infant formula is available only to infants (ages 0 through 12 months) enrolled in a New Jersey plan that includes coverage for prescription drugs or who have a freestanding prescription drug program. Coverage for specialized infant formulas is subject to utilization review, including periodic review, of the continued medical necessity of the specialized infant formula.

- http://www.njleg.state.nj.us/2000/Bills/PL01/361_.HTM

- http://www.njleg.state.nj.us/2000/Bills/S2000/1839_S1.PDF

New Jersey Members with a Pharmacy Benefit
Specialized nonstandard infant formulas are covered only through the pharmacy benefit when all of the following criteria are met:

- The individual is enrolled in a New Jersey product that includes coverage for prescription drugs.
- The individual requires these formulas from birth through 12 months of age.
- The individual has been diagnosed with multiple food protein intolerance and has failed standard non-cow milk-based formulas, including soybean and goat milk.
- The professional provider has determined that specialized infant formulas are medically necessary.
- Continued coverage for specialized infant formulas is subject to utilization review, including periodic review, of the continued medical necessity of the specialized non-standard infant formula.
- Examples of specialized non-standard infant formulas list includes, but is not limited to, the following: Elecare Infant or Jr.; Nutramigen; Progestimil; Neocate Junior or Infant; Portagen; Alimentum; NeoSure

For additional information addressing the New Jersey Specialty Infant Formula Program, contact the individual's Prescription Benefit Plan.

New Jersey Members without a Pharmacy Benefit

- If the individual has a pharmacy benefit with another company, the individual should be directed to seek coverage from that plan.
- If the individual does not have a pharmacy benefit with another plan, only nutritional formulas for individuals with inherited metabolic disorders are covered under the member's medical benefit when the medical necessity criteria contained within the policy are met.
- Coverage of these products is subject to periodic review for continued medical necessity.

All other requests for nutritional formulas are treated as a benefit exclusion.

MEDICAL FOODS AND LOW-PROTEIN MODIFIED FOOD PRODUCTS FOR INBORN ERRORS OF METABOLISM ADMINISTERED ORALLY OR THROUGH A TUBE

For members enrolled in a New Jersey product, An Act concerning coverage for foods and food products for inherited metabolic diseases (Chapter 338, Approved January 12, 1998) Ch 27, 17B:27-46.1r (1998) provides for insurance coverage for the following:

Coverage for the therapeutic treatment of inherited metabolic diseases, including the purchase of medical foods and low-protein modified food products, when the disease is diagnosed and the

treatment is determined to be medically necessary by the individual's physician.

"Low protein modified food product" means a food product that is specially formulated to have less than one gram of protein per serving and is intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease, but does not include a natural food that is naturally low in protein; and "medical food" means a food that is intended for the dietary treatment of a disease or condition for which nutritional requirements are established by medical evaluation and is formulated to be consumed or administered enterally under direction of a physician.

NJ Approved January 12, 1998.

http://www.njleg.state.nj.us/9697/Bills/PL97/338_.HTM.

Medical foods and low protein modified foods are covered under the medical benefit when both of the following criteria are met:

- The individual is diagnosed with an inherited error of metabolism.
- The required medical necessity documentation is provided the individuals' physician.

DONATED HUMAN BREAST MILK

For members enrolled in a New Jersey product, An Act concerning coverage for donated human breast milk (Public Law 2017, c 301; Approved January 16, 2018) provides for insurance coverage for the following:

Expenses incurred in the provision of pasteurized donated human breast milk (including human milk fortifiers) are covered by the Company in accordance with the state mandates for individuals enrolled in a New Jersey product subject to New Jersey's insurance law.

Coverage of pasteurized donated human breast milk, which may include human milk fortifiers, is based on meeting criteria which include the following:
I. The covered person is an infant under the age of six months
II. The milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health
III. The licensed medical practitioner who is prescribing the milk must meet one of the following requirements:

a. The licensed medical practitioner has issued an order for an infant who is medically or physically unable to receive maternal breast milk or participate in breast feeding or whose mother is medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breast feeding despite optimal lactation support; or
b. The licensed medical practitioner has issued an order for an infant who meets any of the following conditions:

1) a body weight below healthy levels determined by the licensed medical practitioner
2) a congenital or acquired condition that places the infant at a high risk for development of necrotizing enterocolitis
3) a congenital or acquired condition that may benefit from the use of donor breast milk as determined by the Department of Health

Coverage for donated human breast milk is subject to utilization review, including periodic review, of the continued medical necessity.

NOTE: If there is no supply of human breast milk that meets the above requirements, the insurer shall not be required to provide coverage of expenses pursuant to this section.

NJ Effective January 1, 2019.

http://www.njleg.state.nj.us/2016/Bills/PL17/309_.PDF.

Version Effective Date: 11/2025

Policy Attachment

Attachment to Policy # 08.00.18q

Attachment: C

Policy #: 08.00.18q

Description: Caloric Requirements

Title: Nutritional Formulas, Enteral Nutrition, Medical Foods, Low-Protein Modified Food Products, and Donated Breast Milk

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Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and

pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

This attachment contains several calculations for the energy requirements for individuals.

CALORIC REQUIREMENTS IN CHILDREN

SAMPLE ESTIMATED ENERGY REQUIREMENTS FOR HEALTHY BOYS AND GIRLS OF MEDIAN WEIGHT AND HEIGHT (FOR AGE AT 50TH PERCENTILE)

Age	**Boys - estimated energy requirements (kcal/kg/day)**			**Girls - estimated energy requirements (kcal/kg/day)**		
0–2 mo	107			104		
3 mo	95			95		
4–35 mo	82			82		
	Boys			**Girls**		
	Median Weight, Boys (kg)	**Sedentary * (kcal/kg/d)**	**Active * (kcal/kg/d)**	**Median Weight, Girls (kg)**	**Sedentary * (kcal/kg/d)**	**Active *(kcal/kg/d)**
3 yr	14.3	80	104	13.9	76	100
4 yr	16.2	74	97	15.8	70	93
5 yr	18.4	68	90	17.9	65	87

6 yr	20.7	63	84	20.2	61	81
7 yr	23.1	59	80	22.8	56	75
8 yr	25.6	56	75	25.6	52	71
9 yr	28.6	53	71	29.0	48	65
10 yr	31.9	49	67	32.9	44	60
11 yr	35.9	46	63	37.2	41	56
12 yr	40.5	44	60	41.6	38	52
13 yr	45.6	42	57	45.8	36	50
14 yr	51.0	40	55	49.4	34	47
15 yr	56.3	39	54	52.0	33	45
16 yr	60.9	38	52	53.9	32	44
17 yr	64.6	36	50	55.1	31	43
18 yr	67.2	35	49	56.2	30	42

* See definition of sedentary and active Physical Activity Level (PAL) below for further information.

References for Caloric Requirements in Children:

Engorn B, Flerlage J. The Harriet Lane Handbook. 20th ed. Philadelphia, PA: Elsevier Saunders; 2015.

Otten JJ, Hellwig JP, Meyers LD, eds. *Dietary Reference Intakes: The Essential Guide to Nutrient Requirements* . Washington, DC: National Academies Press, 2006.

***PHYSICAL ACTIVITY LEVELS (PAL) IN CHILDREN AND ADULTS:**

Physical Activity Coefficients (PA Values) for Use in EER Equations

	Sedentary (PAL* 1.0–1.39)	Low Active (PAL* 1.4–1.59)	Active (PAL* 1.6–1.89)	Very Active (PAL* 1.9–2.5)
	Typical daily living activities (e.g., household tasks, walking to the bus)	Typical daily living activities PLUS 30-60 minutes of daily moderate activity (e.g., walking 5-7 km/h)	Typical daily living activities PLUS at least 60 minutes of daily moderate activity	Typical daily living activities PLUS at least 60 minutes of daily moderate activity PLUS an additional 60 minutes of vigorous activity or 120 minutes of moderate activity
Boys 3–18 y	1.00	1.13	1.26	1.42
Girls 3–18 y	1.00	1.16	1.31	1.56
Men 19 y +	1.00	1.11	1.25	1.48
Women 19 y +	1.00	1.12	1.27	1.45

<u>References for Caloric Requirements in Children:</u>

Coulston A, Boushey CJ, Ferruzzi MG. Nutrition in the Prevention and Treatment of Disease, 3rd Ed. 2013.

Engorn B, Flerlage J. The Harriet Lane Handbook. 20th ed. Philadelphia, PA: Elsevier Saunders; 2015.

Escott-Stump S. Nutrition and Diagnosis - Related Care, 7th Ed. 2012. Wolters Kluwer/Lippincott Williams & Wilkins. Philadelphia, PA.

Otten JJ, Hellwig JP, Meyers LD, eds. *Dietary Reference Intakes: The Essential Guide to Nutrient Requirements* . Washington, DC: National Academies Press, 2006.

CALORIC REQUIREMENTS IN CHILDREN AND ADULTS:

1. Equations based on the following sources: Coulston 2013, Escott-Stump (2012), Otten (2006)

Infants and Young Children
Estimated Energy Requirement (EER) (kcal/day) = Total Energy Expenditure + Energy Deposition 0–3 months EER[a] = (89 X weight [kg] –100) + 175
4–6 months EER = (89 X weight [kg] –100) + 56
7–12 months EER = (89 X weight [kg] –100) + 22
13–35 months EER = (89 X weight [kg] –100) + 20

Children and Adolescents 3–18 years
Estimated Energy Requirement (EER) (kcal/day) = Total Energy Expenditure + Energy Deposition
Boys
3–8 years EER = 88.5 – (61.9 X age [y]) + PAL* X [(26.7 X weight [kg]) + (903 X height [m])] + 20
9–18 years EER = 88.5 – (61.9 X age [y]) + PAL X [(26.7 X weight [kg]) + (903 X height [m])] + 25
Girls
3–8 years EER = 135.3 – (30.8 X age [y]) + PAL X [(10.0 X weight [kg]) + (934 X height [m])] + 20
9–18 years EER = 135.3 – (30.8 X age [y]) + PAL X [(10.0 X weight [kg]) + (934 X height [m])] + 25

Adults 19 years and older
Estimated Energy Requirement (EER) (kcal/day) = Total Energy Expenditure
Men EER = 662 – (9.53 X age [y]) + PAL* X [(15.91 X weight [kg]) + (539.6 X height [m])]
Women EER = 354 – (6.91 X age [y]) + PAL X [(9.36 X weight [kg]) + (726 X height [m])]

Pregnancy
Estimated Energy Requirement (EER) (kcal/day) = Nonpregnant EER + Pregnancy Energy Deposition
1st trimester EER = Nonpregnant EER + 0
2nd trimester EER = Nonpregnant EER + 340
3rd trimester EER = Nonpregnant EER + 452

Lactation
Estimated Energy Requirement (EER) (kcal/day) = Nonpregnant EER + Milk Energy Output – Weight Loss
0–6 months postpartum EER = Nonpregnant EER + 500 – 170
7–12 months postpartum EER = Nonpregnant EER + 400 – 0

NOTE: These equations provide an estimate of energy requirement. Relative body weight (i.e., loss, stable, gain) is the preferred indicator of energy adequacy.
* See definition of sedentary and active Physical Activity Level (PAL) above for further information.

References for Caloric Requirements in Children and Adults:

Coulston A, Boushey CJ, Ferruzzi MG. Nutrition in the Prevention and Treatment of Disease, 3rd Ed. 2013.

Escott-Stump S. Nutrition and Diagnosis - Related Care, 7th Ed. 2012. Wolters Kluwer/Lippincott Williams & Wilkins. Philadelphia, PA.

Otten JJ, Hellwig JP, Meyers LD, eds. *Dietary Reference Intakes: The Essential Guide to Nutrient Requirements* . Washington, DC: National Academies Press, 2006.

2. Harris-Benedict Equations (1919):

REE = Resting Energy Expenditure

Women: REE (kcal/day) = 655 + 9.56 (weight in kg) + 1.85 (height in cm) - 4.68 (age in years)

Men: REE (kcal/day) = 66.5 + 13.75 (weight in kg) + 5 (height in cm) - 6.76 (age in years)

References for Caloric Requirements in Children and Adults:

Coulston A, Boushey CJ, Ferruzzi MG. Nutrition in the Prevention and Treatment of Disease, 3rd Ed. 2013.

Harris JA, Benedict FG. A Biometric Study of Basal Metabolism in Man. Washington, DC: Carnegie Institution, 1919.

3. Harris–Benedict Equations revised by Mifflin and St Jeor (1990):

REE = Resting Energy Expenditure.
Note: REE is usually multiplied by PAL*

Females: REE = 10 X weight (kg) + 6.25 X height (cm) – 5 X age (y) – 161

Males: REE = 10 X weight (kg) + 6.25 X height (cm) – 5 X age (y) + 5

References for Caloric Requirements in Children and Adults:

Mifflin MD, St Jeor ST, Hill LA, Scott BJ, Daugherty SA, Koh YO. A new predictive equation for resting energy expenditure in healthy individuals. *Am J Clin Nutr*. 1990 Feb;51(2):241-7.

CALORIC REQUIREMENTS IN ADULTS:

Short methods for calculating energy needs:

1. Energy Needs Based on Level of Activity or Illness:

	Level of Activity or Illness		
Goal	**Low**	**Moderate**	**High**
Lose weight	15 kcal/kg	20 kcal/kg	25 kcal/kg
Maintain weight	20 kcal/kg	25 kcal/kg	30 kcal/kg
Gain weight	25 kcal/kg	30 kcal/kg	35 kcal/kg

2. Energy Needs Based on Gender:
Note: weight in lbs.

Men or active women	15 kcal/lb
Most women, sedentary men, adults over 55 years	13 kcal/lb
Sedentary women, obese adults	10 kcal/lb
Pregnant women	
1st trimester	13-15 kcal/lb
2nd and 3rd trimester	16-17 kcal/lb
Lactating women	15-17 kcal/lb

References for Caloric Requirements Adults:

Escott-Stump S. Nutrition and Diagnosis - Related Care, 7th Ed. 2012. Wolters Kluwer/Lippincott Williams & Wilkins. Philadelphia, PA.

Version Effective Date: 11/2025

Title: Ocrelizumab (Ocrevus®) and Ocrelizumab and Hyaluronidase-ocsq (Ocrevus Zunovo™)

MEDICALLY NECESSARY

Ocrelizumab (Ocrevus®), administered as an intravenous (IV) infusion, or ocrelizumab and hyaluronidase-ocsq (Ocrevus Zunovo™), as a subcutaneous (SC) injection, are considered medically necessary and, therefore, covered for the treatment of adults with either relapsing forms of multiple sclerosis (RMS) (including clinically isolated syndrome [CIS], relapsing-remitting disease, and active secondary progressive disease) or primary progressive forms of multiple sclerosis (PPMS) when the individual is hepatitis B negative (i.e., has negative results for hepatitis B surface antigen [HBsAg] and anti-hepatitis B virus tests).

EXPERIMENTAL/INVESTIGATIONAL

All other uses for ocrelizumab (Ocrevus) or ocrelizumab and hyaluronidase-ocsq (Ocrevus Zunovo), including nonrelapsing secondary progressive MS, are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Octreotide Acetate (Sandostatin® LAR Depot)

MEDICALLY NECESSARY

Octreotide acetate (Sandostatin LAR Depot) is considered medically necessary and, therefore, covered for the long-term
treatment of any of the following conditions in individuals who have already started therapy wit h octreotide acetate (Sandostatin) immediate-release formulation, when the corresponding Dosing and Frequency Requirements are met:

- Acromegaly
    - For the management of individuals who had inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy was not an option
    - Dosage and frequency up to 40 mg every 4 weeks
- Metastatic Carcinoid Tumors
    - For the management of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
    - Dosage and frequency up to 30 mg every 4 weeks
- Neuroendocrine and Adrenal Tumors (See corresponding Dosing and Frequency Requirements, listed after each condition)
    - Neuroendocrine Tumors of the GI Tract (well-differentiated Grade 1/2), Lung, and Thymus
        - As primary treatment for symptom and /or tumor control for unresected primary gastrinoma
        - For symptom control in individuals with carcinoid syndrome:
            - as a single agent
            - in combination with telotristat (Xermelo) for persistent diarrhea due to poorly controlled carcinoid syndrome
            - in combination with other systemic therapies (based on disease site) with or without telotristat (Xermelo) for persistent symptoms such as flushing or diarrhea due to poorly controlled carcinoid syndrome

- For symptom and/or tumor control of recurrent, locoregional advanced disease and/or distant metastases* of the gastrointestinal tract
    - as a single agent if unresectable and a low tumor burden
    - as a single agent for disease progression (if not already receiving) following resection of primary + metastases
    - as a single agent for disease progression (if not already receiving) following observation unresectable low tumor burden
    - as a single agent following resection of primary tumor if unresectable and locally symptomatic from primary tumor
    - as a single agent or in combination with alternative front-line therapy if clinically significant tumor burden
    - as a single agent as subsequent therapy at above label dosing after clinical, symptomatic, or radiographic progression (if SSTR-positive) on standard doses

- For symptom and/or tumor control of recurrent and/or locoregional unresectable bronchopulmonary/thymic disease* if somatostatin receptor positive and/or hormonal symptoms
    - as primary therapy
    - as subsequent therapy (as alternate primary therapy) if progression on primary therapy
- For symptom and/or tumor control of recurrent and/or distant metastatic bronchopulmonary/thymic disease* if somatostatin receptor positive and/or hormonal symptoms (preferred if clinically significant tumor burden and low grade (typical carcinoid), evidence of disease progression, intermediate grade (atypical carcinoid histology), or symptomatic.
    - as primary therapy
    - as subsequent therapy (as alternate primary therapy) if progression on primary therapy if clinically significant tumor burden and low grade (typical carcinoid), evidence of disease progression, intermediate grade (atypical carcinoid histology), or symptomatic
    - at above label dosing if clinically significant tumor burden and low grade (typical carcinoid), evidence of disease progression,

intermediate grade (atypical carcinoid histology), or symptomatic after clinical, symptomatic, or radiographic progression (if SSTR-positive and/or hormonal symptoms) on standard doses

- For symptom and/or tumor control of multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH) chronic cough/dyspnea is not responsive to inhalers as primary therapy
- Dosage and frequency up to 30 mg every four weeks until disease progression or unacceptable toxicity

- Neuroendocrine Tumors of the Pancreas (Islet Cell Tumors) (well-differentiated Grade 1/2)
  - For the management of symptoms and /or tumor control of locoregional disease
    - for gastrinoma (usually duodenal or head of pancreas)
    - insulinoma only if tumor expresses somatostatin receptors
    - for glucagonoma (usually tail)
    - for VIPoma
  - For symptom and/or tumor control as subsequent therapy at above label dosing after clinical, symptomatic or radiographic progression on standard doses (if SSTR-positive)
  - For NCCN-Preferred for symptoms and /or tumor control in individuals** with recurrent or locoregional advanced disease and/or distant metastatic disease* if somatostatin receptor (SSTR) -positive
    - as a single agent for asymptomatic, low tumor burden and stable disease
    - as a single agent for symptomatic, clinically significant tumor burden, or clinically significant progression (if disease progression and not already receiving)
    - in combination with alternative front-line therapy for symptomatic, clinically significant tumor burden, or clinically

significant progression

        - Dosage and frequency up to 30 mg every four weeks until disease progression or unacceptable toxicity
    - Pheochromocytoma/Paraganglioma
        - As primary treatment of either of the following:
            - for hormone excess and symptom control of locally unresectable disease or distant metastases (if SSTR-positive) of secreting tumors
        - Dosage and frequency up to 30 mg every four weeks
    - Neuroendocrine Tumors: well-differentiated Grade 3, as treatment of symptoms and /or tumor (if SSTR-positive and/or hormonal symptoms) for unresectable locally advanced/metastatic disease with favorable biology (e.g. relatively low Ki-67 [<55%], positive SSTR-based PET imaging)
        - Dosage and frequency up to 30 mg every four weeks until disease progression or unacceptable toxicity
- Thymomas and Thymic Carcinomas
    - Preoperative systemic therapy if octreotide scan or dotatate PET/CT positive with or without prednisone for individuals who cannot tolerate first-line combination regimens for thymoma for surgically resectable disease if R0 resection is considered uncertain
    - Postoperative treatment if octreotide scan or dotatate PET/CT positive with or without prednisone for individuals who cannot tolerate first-line combination regimens for thymoma after R2 resection
    - First-line therapy if octreotide scan or dotatate PET/CT positive with or without prednisone for individuals who cannot tolerate first-line combination regimens for:
        - potentially resectable locally advanced disease
        - potentially resectable solitary metastasis or ipsilateral pleural metastasis
        - following surgery for solitary metastasis or ipsilateral pleural metastasis

        - medically inoperable/unresectable solitary metastasis or ipsilateral pleural metastasis

        - extrathoracic metastatic disease

    - Second-line therapy if octreotide scan or dotatate PET/CT positive with or without prednisone for:
        - unresectable locally advanced disease

        - solitary metastasis or ipsilateral pleural metastasis

        - extrathoracic metastatic disease

    - Dosage and frequency up to 30 mg every four weeks until disease progression or unacceptable toxicity

- Central Nervous System Cancers - Meningiomas
    - in combination with everolimus for surgically inaccessible recurrent or progressive disease when radiation is not possible
    - Dosage and frequency up to 30 mg every 4 weeks until disease progression or unacceptable toxicity

- Vasoactive Intestinal Peptide (VIP)-secreting Tumors

Per NCCN:

*If disease progression, treatment with octreotide LAR should be continued in individuals with functional tumors and may be used in combination with any of the systemic therapy options.
**For individuals with insulinoma, octreotide should be used only if somatostatin scintigraphy is positive.

MANDATES

PENNSYLVANIA MEMBERS
In accordance with the Commonwealth of Pennsylvania's Act 6 of 2020 or Fair Access to Cancer Treatment Act, for members who are enrolled in Pennsylvania commercial products who have Stage 4, advanced metastatic cancer, refer to the Medical Policy titled Coverage of Anticancer Prescription Oral and Injectable Drugs and Biologics and Supportive agents (08.01.08) for additional information regarding the applicable coverage of drugs and biologics.

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Off-label Coverage for Prescription Drugs and/or Biologics

Policy

Coverage is subject to the terms, conditions, and limitations of the member's contract.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

CRITERIA TO ESTABLISH MEDICAL NECESSITY FOR OFF-LABEL COVERAGE OF US FOOD AND DRUG ADMINISTRATION (FDA)--APPROVED DRUGS AND/OR BIOLOGICS

Off-label use of prescription drugs and/or biologics can include factors such as indications, dosages, frequencies, or routes of administration that are inconsistent with US Food and Drug Administration (FDA) labeling. For off-label use, additional clinical rationale is required to support coverage.

Off-label use of prescription drugs and/or biologics is considered medically necessary and, therefore, covered when the off-label use is supported by either the Company-recognized prescription drug and/or biologic compendia, or published research, as outlined below.

1. COMPENDIA FOR ONCOLOGIC USE (ANTI-CANCER CHEMOTHERAPY)

For coverage of an anti-cancer chemotherapy regimen, the off-label use is considered medically necessary and therefore covered when one of the following criteria is met:

- The narrative text in American Hospital Formulary Service--Drug Information (AHFS-DI®) is supportive of the use.
- The use is classified as Category 1 or 2A by National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium™.
- The use is classified as Class I or Class IIa in Micromedex® DrugDex® Compendium.

An anti-cancer chemotherapy regimen is considered experimental/investigational even when above criteria have been met, and when one of the following exists:

- The use is classified as Category 3 by NCCN® or Class III in Micromedex® DrugDex®.
- The narrative text in AHFS-DI® is not supportive of the use.

- Any of the compendia listed above state that the prescription drug and/or biologic is not indicated, is unsupported, is not recommended, or equivalent terms are used regarding the prescription drug and/or biologic

When a compendia is considered neither supportive nor non-supportive (ie, Category 2B in NCCN, Class IIb in Micromedex® DrugDex®, or an absence of narrative text or evidence classification from any Company-recognized compendium), please refer to the section in this policy entitled Published Clinical Research.

2. COMPENDIA FOR NON-ONCOLOGIC USE

For coverage of non-oncologic prescription drugs and/or biologics, the off-label use is considered medically necessary and therefore covered when one of the following exists:

- The narrative text in American Hospital Formulary Service--Drug Information (AHFS-DI®) is supportive of the use.
- The use is classified as Class I or Class IIa in Micromedex® DrugDex® Compendium.

Non-oncologic drugs and/or biologics are considered experimental/investigational and therefore not covered, even when the above criteria have been met, and when one of the following exists:

- The use is classified as Class III in Micromedex® DrugDex®.
- The narrative text in AHFS-DI® is not supportive of the use.
- Either of the compendia listed above state that the prescription drug and/or biologic is not indicated, is unsupported, is not recommended, or equivalent terms are used regarding the prescription drug and/or biologic.

When a compendia is considered neither supportive nor non-supportive (i.e., Class IIb in Micromedex® DrugDex®, or an absence of narrative text or evidence classification from any Company-recognized compendium), please refer to the section in this policy entitled Published Clinical Research.

3. PUBLISHED CLINICAL RESEARCH

In order for an off-label use to be supported by published clinical research, all of the following criteria must be met:

- The prescription drug and/or biologic must have been studied in at least two clinical trials conducted at different centers, and the results must have been published in national or international peer-reviewed journals with an editorial committee composed of physicians. Peer-reviewed medical literature includes scientific, medical, and pharmaceutical publications. It does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).
    - A use is considered supported by clinical research when it appears in at least two Phase III clinical trials that have definitively demonstrated its safety and effectiveness as an appropriate medical treatment for the condition. If no Phase III trial evidence is available, at least two Phase II clinical trials with reasonably large patient samples showing consistent results of safety and efficacy may be considered in certain instances (e.g., in rare diseases in which a Phase III study might be difficult to complete in a reasonable period of time after completion of the Phase II studies, or when overwhelmingly good evidence of safety and effectiveness is noted in the Phase II studies).
- Reliable evidence must demonstrate that the proposed off-label use for the specified medical condition is safe and effective and that the beneficial effects of the treatment outweigh its risks.
- In determining whether there is supportive clinical evidence for a particular use of a prescription drug and/or biologic, the quality of the evidence in published, peer-reviewed medical literature is considered. Among other things, such consideration involves the assessment of the following:
    - The prevalence and life history of the disease when evaluating the adequacy of the number of subjects and the response rate
    - The effect on the individual's well-being and other responses to therapy that indicate effectiveness (e.g., reduction in mortality, morbidity, and signs and symptoms)
    - Whether the clinical characteristics of the beneficiary and the use are adequately represented in the published evidence
    - Whether the study is appropriate to address the clinical question, such as:
        - If the study design is appropriate to address investigative questions (e.g., in some clinical studies, it may be unnecessary or not feasible to use randomization, double-blind trials, placebos, or crossover)
        - If non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of prescription drug and/or biologic

    - Generally, case reports are considered uncontrolled, are based on anecdotal information, and do not provide adequate supportive clinical evidence for determining accepted uses of prescription drugs and/or biologics

- The off-label use is supported by published clinical research, and the results have been published in major peer-reviewed medical journals such as, but not limited to:

• *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*	• *Gynecologic Oncology* • *International Journal of Radiation, Oncology, Biology, and Physics* • *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* • *Radiation Oncology* • *The Journal of the American Medical Association* • *The New England Journal of Medicine*

EXPERIMENTAL/INVESTIGATIONAL

Prescription drugs and/or biologics that are considered experimental/investigational are not covered because the safety and/or effectiveness of the prescription drug and/or biologic cannot be established by a review of the available published peer-reviewed literature. Prescription drugs and/or biologics are considered experimental/investigational for any of the following:

- The prescription drug and/or biologic has not received US Food and Drug Administration (FDA) approval for any use.
- The off-label use of the prescription drug and/or biologic does not meet the medical necessity criteria listed in this policy or in any other specific Company Medical Policy addressing a drug and/or biologic (i.e., the off-label use is not recognized by the appropriate compendia or published clinical research). This includes products granted orphan designation by the FDA.
- The FDA determines a prescription drug and/or biologic to be contraindicated for specific condition(s) or specific off-label use(s).
- The off-label use is not medically accepted or not indicated by a compendium for specific conditions (i.e., the use is a Category 3 in NCCN, Class III in Micromedex® DrugDex®, or when the narrative text in AHFS-DI® is not supportive.)
    - The absence of narrative text for an off-label use is considered neither supportive nor non-supportive.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the prescription drug and/or biologic.

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: patisiran (Onpattro®) and vutrisiran (Amvuttra®)

MEDICALLY NECESSARY

INITIAL THERAPY
Patisiran (Onpattro) or vutrisiran (Amvuttra) are considered medically necessary and, therefore, covered for individuals 18 years of age or older with hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy when all of the following criteria**,** including Dosing and Frequency Requirements listed below, are met:

- Diagnosis of hATTR amyloidosis with polyneuropathy is confirmed by molecular genetic testing that reveals pathogenic variation(s) in the transthyretin (TTR) gene (e.g., variation of V30M, which is the most common pathogenic variant consisting of a point mutation)
- Documentation of one of the following baseline ambulation parameters in either the Familial Amyloid Polyneuropathy (FAP) Stage or Polyneuropathy Disability (PND) Score (see Guidelines Section for description of scores):
    - Stage 1 (unimpaired ambulation) or 2 (assisted ambulation) on the FAP staging tool
    - Score 0, I, II, IIIa, or IIIb on the PND scoring tool
- Documented presence of cardiac or renal manifestations, or motor, sensory, or autonomic neuropathy related to the hATTR amyloidosis with polyneuropathy (e.g., neuropathic pain, muscle weakness that affects daily living, orthostatic hypotension, diarrhea, nausea, vomiting, heart failure, arrhythmias, proteinuria, renal failure; vision disorders, such as vitreous opacity, dry eyes, glaucoma, or pupils with an irregular or scalloped appearance)
- Prescribed by or in consultation with a neurologist, geneticist, or professional provider specializing in the treatment of amyloidosis
- Individual has not had a liver transplant or is unlikely to be a candidate
- Patisiran (Onpattro) or vutrisiran (Amvuttra) will not be used in combination with any other RNA interference agents (e.g., eplontersen [Wainua], inotersen [Tegsedi]), or transthyretin stabilizers (e.g., tafamidis [Vyndaqel, Vyndamax])

CONTINUATION THERAPY (AFTER 18 MONTHS OF THERAPY)
Patisiran (Onpattro) or vutrisiran (Amvuttra) are considered medically necessary and, therefore, covered for continuation therapy following at least 18 months of therapy for the treatment of hATTR amyloidosis with polyneuropathy when the individual meets both of the following criteria:

- Recent documentation of one of the following ambulation parameters (see Guidelines section for description of scores):
    - Stage 1 (unimpaired ambulation) or 2 (assisted ambulation) on the FAP staging tool
    - Score 0, I, II, IIIa, or IIIb on the PND scoring tool
- Documented improvement or stability in the signs and symptoms of hATTR amyloidosis with polyneuropathy (e.g., neuropathic pain, muscle weakness that affects daily living, orthostatic hypotension, diarrhea, nausea, vomiting, heart failure, arrhythmias, proteinuria, renal failure; vision disorders, such as vitreous opacity, dry eyes, glaucoma, or pupils with an irregular or scalloped appearance), based on objective or standard evaluation scales

NOTE:

Evio has been selected by the Company to administer clinical outcomes monitoring for patients receiving certain high-cost drug therapies. Patisiran (Onpattro) and vutrisiran (Amvuttra) are included in the portfolio of high-cost drug therapies for which Evio will be tracking clinical outcomes. If a patient meets all medical policy provisions and is approved to receive treatment, the requesting professional provider or member must attest and agree to providing clinical outcomes data and information via Evio's secure web portal as requested.

DOSING AND FREQUENCY REQUIREMENTS

PATISIRAN (ONPATTRO)
The following dosing and frequency information was taken from the prescribing information for this product:

- Individuals weighing less than 100 kg: the dosage is 0.3 mg/kg once every 3 weeks via intravenous infusion
- Individuals weighing 100 kg or more: the dosage is 30 mg once every 3 weeks via intravenous infusion

VUTRISIRAN (AMVUTTRA)

The following dosing and frequency information was taken from the prescribing information for this product: the recommended dosage is 25 mg administered by subcutaneous injection by a professional provider once every 3 months.

REQUIREMENTS

The Company reserves the right to modify the dosing and frequency requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of patisiran (Onpattro) or vutrisiran (Amvuttra). Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to, the US Food and Drug Administration (FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of patisiran (Onpattro) or vutrisiran (Amvuttra) outside of the dosing and frequency requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the utilization management activities. The Company reserves the right to conduct postpayment review and audit procedures for any claims submitted for patisiran (Onpattro) or vutrisiran (Amvuttra).

NOT MEDICALLY NECESSARY

When molecular genetic testing reveals results showing established benign variation(s) or wild-type genotype in the TTR gene, patisiran (Onpattro) or vutrisiran (Amvuttra) are considered not medically necessary and, therefore, not covered because the available published peer-reviewed literature does not support their uses as treatments.

EXPERIMENTAL/INVESTIGATIONAL

When molecular genetic testing reveals likely pathogenic or variations of unknown significance (VUS) in the TTR gene, the use of patisiran (Onpattro) or vutrisiran (Amvuttra) are considered experimental/investigational and, therefore, not covered because the safety and/or effectiveness of this service cannot be established by review of the available published peer-reviewed literature.

The use of patisiran (Onpattro) or vutrisiran (Amvuttra) for hATTR amyloidosis with cardiomyopathy in those who are not experiencing polyneuropathy is considered experimental/investigational and, therefore, not covered because the safety and/or effectiveness of this service cannot be established by review of the available published peer-reviewed literature.

All other uses for patisiran (Onpattro) and vutrisiran (Amvuttra) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

When coverage of patisiran (Onpattro) or vutrisiran (Amvuttra) are requested outside of the dosing and frequency requirements listed in this policy, the prescribing professional provider must supply documentation (i.e., published peer-reviewed literature) to the Company that supports this request.

Duration of authorization: 12 months

Version Effective Date: 10/21/2024

Title: Pegloticase (Krystexxa®)

MEDICALLY NECESSARY

INITIAL THERAPY
Pegloticase (Krystexxa) is considered medically necessary and, therefore, covered for the treatment of symptomatic chronic gout in adult individuals when all of the following criteria, including Dosing and Frequency Requirements, are met:

- Failure to normalize uric acid levels to less than 6 mg/dL after at least three months of one xanthine oxidase inhibitor (XOI) (e.g., allopurinol or febuxostat) at the maximum recommended dose (alone or in combination with probenecid), unless the individual is intolerant to, has had a toxic reaction to, or has a contraindication to taking XOI.

- Individual has at least one of the following:
    - at least two gout flares in the previous 12 months
    - at least one gout tophus
    - gouty arthritis
- Pegloticase (Krystexxa) must be used in combination with weekly oral methotrexate, unless intolerant, contraindicated, or not clinically appropriate
- Dosing and frequency: 8 mg IV infusion every 2 weeks

CONTINUATION THERAPY

Pegloticase (Krystexxa) is considered medically necessary and, therefore, covered for the continued treatment of symptomatic chronic gout in adult individuals when both of the following are met:

- There is documented improvement in clinical signs and symptoms, such as reduction of uric acid levels to less than 6 mg/dL, gout flare reduction, tophus reduction/resolution , reduction in joint pain/swelling.
- Dosing and frequency: 8 mg IV infusion every 2 weeks

DOSING AND FREQUENCY REQUIREMENTS

The Company reserves the right to modify the Dosing and Frequency Requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of pegloticase (Krystexxa). Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to: the US Food and Drug Administration

(FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of pegloticase (Krystexxa) outside of the Dosing and Frequency Requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the utilization management activities. The Company reserves the right to conduct post-payment review and audit procedures for any claims submitted for pegloticase (Krystexxa).

EXPERIMENTAL INVESTIGATIONAL

The use of pegloticase (Krystexxa) for non-adults or for individuals with asymptomatic hyperuricemia is considered experimental/investigational and, therefore, not covered because the safety and/or effectiveness of this use cannot be established by review of the available published peer-reviewed literature.

All other uses for pegloticase (Krystexxa) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

When coverage of pegloticase (Krystexxa) is requested outside of the Dosing and Frequency Requirements listed in this policy, the prescribing professional provider must supply documentation (i.e., published peer-reviewed literature) to the Company that supports this request.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Photodynamic Therapy (PDT) Using Levulan® Kerastick® or Ameluz® (Aminolevulinic Acid HCl [ALA])

MEDICALLY NECESSARY:

Photodynamic therapy (PDT) using Levulan Kerastick with the BLU-U Blue Light Photodynamic Therapy Illuminator is considered medically necessary and, therefore, covered for any of the following indications:

- Field cancerization/confluent epidermal displasia
    - Treatment of non-hyperkeratotic actinic keratoses of the face, scalp, or upper extremities
    - Treatment of squamous cell carcinoma in situ (Bowen's disease) in individuals only when surgery AND radiation therapy are contraindicated
- Treatment of superficial basal cell carcinoma in individuals only when surgery AND radiation therapy are contraindicated

PDT using Ameluz with BF RhodoLED lamp is considered medically necessary and, therefore, covered for any of the following indications:

- Field cancerization/confluent epidermal displasia
    - Treatment of non-hyperkeratotic actinic keratoses of the face, scalp, or upper extremities
    - Treatment of squamous cell carcinoma in situ (Bowen's disease) in individuals only when surgery AND radiation therapy are contraindicated
- Treatment of superficial basal cell carcinoma in individuals only when surgery AND radiation therapy are contraindicated

Duration of authorization: 12 months

Version Effective Date: 11/2025

Title: Pozelimab-bbfg (Veopoz TM)

MEDICALLY NECESSARY

INITIAL THERAPY

Pozelimab-bbfg (Veopoz™) is considered medically necessary and, therefore, covered for the treatment of individuals one year of age and older with cluster of differentiation (CD)55-deficient protein-losing enteropathy (PLE), also known as CHAPLE (complement hyperactivation, angiopathic thrombosis and protein-losing enteropathy) disease, when **all** of the following are met:

- Presence of laboratory-confirmed genotype of biallelic CD55 loss-of-function mutation
- Presence of at least **one** of the following symptoms, attributable to CHAPLE disease, within the last six months (unless the individual is currently being treated with eculizumab [Soliris®] therapy with the willingness by the professional provider to discontinue the treatment before initiating treatment with pozelimab-bbfg [Veopoz]):
    - Hypoalbuminemia (serum albumin concentration of 3.2 g/dL or less)
    - Facial edema
    - Peripheral edema
    - Diarrhea
    - Abdominal pain
    - Thromboembolic event(s)
- Completion or update of meningococcal vaccination (in serogroups A, C, W and Y, and serogroup B) at least two weeks prior to the planned start of pozelimab-bbfg (Veopoz) therapy unless the risks of delaying therapy outweigh the risks of developing meningococcal infection (follow the most current Advisory Committee on Immunization Practices [ACIP] recommendations for meningococcal vaccination)
- Pozelimab-bbfg (Veopoz) is ordered by, or in consultation with, a professional provider who has the expertise to treat CHAPLE disease (e.g., Gastroenterology, Hematology, Immunology, rare genetic hematologic disease specialist)
- The individual will not be concurrently treated with any other complement inhibitors
- The individual does not have unresolved Neisseria meningitidis infection at the start of treatment with pozelimab-bbfg (Veopoz)

CONTINUATION THERAPY
Continuation of pozelimab-bbfg (Veopoz) will be considered to be medically necessary when all of the following are met:

- Hypoalbuminemia has improved or resolved from baseline levels
- Symptoms have improved or resolved from baseline levels

EXPERIMENTAL/INVESTIGATIONAL

All other uses of pozelimab-bbfg (Veopoz) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Prior Authorization Group Description	**Primary Hemophagocytic Lymphohistiocytosis (HLH) Agents**
Drugs	Gamifant (emapalumab-lzsg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members who have undergone hematopoietic stem cell transplantation (HSCT)
Required Medical Information	"See Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders
Coverage Duration	If all the criteria are met, initial requests will be approved with up to a 1 month duration. If all the criteria are met, reauthorization requests will be approved with up to a 3 month duration.
Other Criteria Revision/Review Date 11/2025	***Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT*** **Initial Authorization** • Member has a diagnosis of Primary HLH • Prescriber attests that member has not achieved a satisfactory response to or is intolerant to conventional HLH therapy (e.g., etoposide, dexamethasone) or has recurrent disease. • Prescriber attests that the member is a candidate for hematopoietic stem cell transplant (HSCT) • Member has been screened for latent tuberculosis infection. • Member has or will receive prophylactic pre-medications (e.g., antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections • Dosing is consistent with FDA approved labeling **Reauthorization** • Member continues to meet initial authorization criteria. • Member is receiving prophylactic pre-medications (e.g., antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Reblozyl (luspatercept-aamt)**
Drugs	Reblozyl (luspatercept-aamt) vial for subcutaneous injection
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members are excluded if they have hemoglobin S/beta-thalassemia, isolated alpha-thalassemia
Required Medical Information	See "other criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or oncologist
Coverage Duration	Initial and reauthorization requests will be approved for 6 months.

Other Criteria	**Criteria for initial approval:**
	• Requested dose is appropriate per labeling
	• The member's weight has been provided with the request
	• The member's most recent hemoglobin level (within the last month) has been provided with the request
	• Diagnosis appropriate per Covered Uses
	• For requests for anemia due to beta thalassemia, documentation of all of the following is required:
	  o Member requires regular red blood cell (RBC) transfusions (defined as at least 6 RBC units received over the last 6 months).
	• For requests for anemia due to myelodysplastic syndrome, documentation of all of the following is required:
	  o Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as very low, low, or intermediate risk of progression.
	  o Member has required transfusion of 2 or more RBC units within an 8 week period in the last 4 months
	  o Hemoglobin less than 10 g/dl
	Reauthorization:
	• For diagnosis of anemia due to beta thalassemia, documentation of the following:
	  o Fewer transfusions compared with baseline
	  AND
	  o A reduction in transfusion requirement of at least 2 RBC units compared with baseline
	• Diagnosis of anemia due to myelodysplastic syndrome: documentation of ONE of the following:

Revision/Review Date: 2/2026	○ Hemoglobin increase of at least 1.5 g/dl from baseline over a period of 8-12 weeks OR ○ Reduction in red blood cell transfusion by at least 4 units over a period of 8-12 weeks compared with baseline transfusion requirement **If the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.**

Title: Repository Corticotropin Injection (Acthar® Gel, Purified Cortrophin[TM] Gel)

MEDICALLY NECESSARY

WEST SYNDROME

Repository corticotropin injection (Acthar Gel) for West syndrome (infantile spasms) is considered medically necessary and, therefore, covered for a period of 12 months when both of the following criteria are met:

- The individual is diagnosed with West syndrome (infantile spasms)
- The individual is 2 years of age or younger

In accordance with the US Food and Drug Administration (FDA)-approved prescribing information labeling, repository corticotropin injection (Acthar Gel) dosing for the treatment of West syndrome (infantile spasms) is as follows:

- Dosage should be given via intramuscular injections of 75 U/m^2 twice daily
- Dosing should be tapered after 2 weeks and eventually discontinued over a 2-week period to avoid adrenal insufficiency
- Tapering schedule: 30 U/m^2 in the morning for 3 days, 15 U/m^2 in the morning for 3 days, 10 U/m^2 in the morning for 3 days, then 10 U/m^2 every other morning for 6 days

NOT MEDICALLY NECESSARY

MULTIPLE SCLEROSIS

The Company's products contain a definition of medical necessity that includes a requirement that a service not be more costly than an alternative service that is at least as likely to produce equivalent therapeutic or diagnostic results for the treatment of that individual's illness. Repository corticotropin injection (Acthar Gel, Purified Cortrophin Gel) is considered not medically necessary and, therefore, not covered for the treatment of acute exacerbations of multiple sclerosis because it is more costly than an alternative service that is at least as likely to produce equivalent therapeutic results for that individual's illness.

OTHER INDICATIONS

Coverage for repository corticotropin injection (Acthar Gel, Purified Cortrophin Gel) for the treatment of additional indications on the prescribing label may depend on the Company's applicable health benefit plan definition of medical necessity. The Company's products contain definitions of medical necessity that include a requirement that a service be covered in accordance with generally accepted standards of medical practice. Generally accepted standards of medical practice means standards that are based on all of the following:

- Credible scientific evidence, published in peer-reviewed medical literature that is generally recognized by the relevant medical community
- Physician specialty society recommendations
- Views of physicians practicing in relevant clinical areas
- Other relevant factors

Because repository corticotropin injection (Acthar Gel, Purified Cortrophin Gel) for the treatment of conditions other than West syndrome is not based on generally accepted standards of medical practice and does not meet the requirement that a service not be more costly than an alternative service that is at least as likely to produce equivalent therapeutic or diagnostic results to the treatment of that individual's illness, repository corticotropin injection (Acthar Gel, Purified Cortrophin Gel) is considered not medically necessary for additional indications under those benefit plans. Some examples of indications that are considered not medically necessary and, therefore, not covered are:

- Rheumatic disorders: psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis,

acute gouty arthritis (Purified Cortrophin Gel)

- Collagen disease: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- Dermatologic disease: severe erythema multiforme, Stevens-Johnson syndrome, severe psoriasis (Purified Cortrophin Gel)
- Allergic states: serum sickness, atopic dermatitis (Purified Cortrophin Gel)
- Ophthalmic diseases: keratitis, iritis, iridocyclitis, diffuse posterior uveitis, choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation, allergic conjunctivitis (Purified Cortrophin Gel)
- Respiratory: symptomatic sarcoidosis
- 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
- Corticosteroid-responsive conditions
- Diagnostic testing for adrenocortical function

OFF-LABEL INDICATIONS

Repository corticotropin injection (Acthar Gel, Purified Cortrophin Gel) is considered not medically necessary and, therefore, not covered for any indications supported as an off-label indication, by the Company's medical policy on off-label coverage for prescription drugs and biologics due to the lack of supporting evidence of effectiveness and safety through controlled clinical studies or clinical practice guidelines.

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Risankizumab-rzaa (Skyrizi®) for Intravenous Use

MEDICALLY NECESSARY

ULCERATIVE COLITIS

Risankizumab-rzaa (Skyrizi) for intravenous use is considered medically necessary and, therefore, covered for moderately to severely active ulcerative colitis when all of the following criteria, including dosing and frequency, are met:

- The individual is 18 years of age or older
- There is documentation of inadequate response, contraindication, or intolerance to conventional (nonadvanced) and/or advanced therapies of at least one of the following:
    - Corticosteroids (e.g., budesonide, prednisone, hydrocortisone, methylprednisolone)
    - Biologic therapy (e.g., infliximab [Remicade]), adalimumab [Humira], golimumab [Simponi Aria], vedolizumab [Entyvio])
    - Immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate)
    - JAK Inhibitors (e.g., tofacitinib [Xeljanz], Upadacitinib [Rinvoq])
    - S1P receptor modulators (e.g., ozanimod [Zeposia])
- Prescribed by or in consultation with a gastroenterologist
- No concurrent use with any other biologic therapy (i.e., tumor necrosis factor antagonists)
- Dosing and frequency: induction dosage is 1200 mg administered by intravenous infusion at Week 0, Week 4, and Week 8. The recommended maintenance dosage is 180 mg or 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter.

CROHN'S DISEASE

Risankizumab-rzaa (Skyrizi) for intravenous use is considered medically necessary and, therefore, covered for moderately to severely active Crohn's disease when all of the following criteria, including dosing and frequency, are met:

- The individual is 18 years of age or older
- There is documentation of failure, contraindication, or intolerance to a trial of at least one of the following:

    - Corticosteroids (e.g., budesonide [Entocort EC], prednisone, hydrocortisone, methylprednisolone)
    - Immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate)
    - Biologic therapy (e.g., certolizumab [Cimzia], adalimumab [Humira], infliximab [Remicade]), ustekinumab (Stelara), vedolizumab [Entyvio])
- Prescribed by or in consultation with a gastroenterologist
- No concurrent use with any other biologic therapy (i.e., tumor necrosis factor antagonists)
- Dosing and frequency: 600 mg administered by intravenous infusion at Weeks 0, 4, and 8. (Maintenance doses are administered by subcutaneous injection.)

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Rituximab

Drugs:

Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human, recombinant)
Truxima (rituximab-abbs)
Ruxience (rituximab-pvvr)
Riabni (rituximab-arrx)

RITUXIMAB WILL BE APPROVED IF THE FOLLOWING PRIOR AUTHORIZATION CRITERIA IS MET:

MULTIPLE SCLEROSIS:

- Refer to the "Healthcare Professional (HCP) administered/IV Disease Modifying Therapies (DMTs) for Multiple Sclerosis (MS)" policy

NEUORMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):

- Refer to the "Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents" policy

RHEUMATOID ARTHRITIS:

Initial Authorization

- The medication is being recommended and prescribed by a rheumatologist.
- The patient is an adult (≥18 y/o) and has a documented clinical diagnosis of rheumatoid arthritis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates and doses) of 3 months or more of therapy with one conventional (non-biologic) DMARD (e.g. methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) or has a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing any of these therapies to manage their medical condition.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses) of 2 preferred biologics indicated for rheumatoid arthritis, or has documented medical reason (intolerance, hypersensitivity, etc.) for not taking the preferred therapies to manage their medical condition.
- Documentation indicating that rituximab is being used concurrently with methotrexate, or a medical reason why methotrexate cannot be used.
- Documentation indicating that the patient has been screened for Hepatitis B Virus (HBV) prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- The member has been receiving rituximab and documentation is provided that a rheumatologist has reevaluated the member and recommends continuation of therapy.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- At least 16 weeks (4 months) has elapsed since the previous course of rituximab therapy.
- Documentation indicating that rituximab is being used concurrently with methotrexate, or a medical reason why methotrexate cannot be used.
- Rituximab is being prescribed at an FDA approved dosage.

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

PEMPHIGUS VULGARIS

Initial Authorization

- The medication is being recommended and prescribed by a rheumatologist or dermatologist
- The patient is ≥ 18 years with a diagnosis of moderate to severe pemphigus vulgaris
- Documentation the patient will be receiving P. jirovecii pneumonia (PJP) prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment
- Rituximab is being prescribed at an FDA approved dose/frequency
- Rituximab is being used in combination with a tapering course of glucocorticoids

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- Documentation of clinical benefits (e.g., absence of new lesions) with rituximab therapy was provided by a rheumatologist or dermatologist
- Documentation the patient will continue to receive PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Rituximab is being prescribed at an FDA approved dose/frequency

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

ONCOLOGY INDICATIONS

Initial Authorization:

- The medication is being recommended and prescribed by an oncologist.
- The medication is being requested for a labeled indication or an indication supported by a NCCN category 1 or 2A level of evidence.
- The requested indication is CD20 positive.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or the National Comprehensive Cancer Network (NCCN) or American Society of Clinical Oncology (ASCO) standard of care guidelines.
- If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.
- If the request is for Rituxan Hycela (rituximab/hyaluronidase human, recombinant), all of the following: the patient has received at least one full dose of a rituximab product by intravenous infusion, the medication is being requested for a malignant condition, and there is a medical reason why the alternative rituximab product cannot be continued.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- The medication is being recommended and prescribed by an oncologist.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or per the NCCN or ASCO standard of care guidelines.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

GRANULOMATOSIS WITH POLYANGIITIS (GPA) (WEGENER'S GRANULOMATOSIS) AND MICROSCOPIC POLYANGIITIS (MPA):

Initial Authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- The patient is 2 years of age or older and has a documented clinical diagnosis of GPA (Wegener's Granulomatosis), eosinophilic granulomatosis with polyangiitis (EGPA), or MPA AND the prescriber indicates whether there is severe or non-severe disease.
- Documentation indicating that rituximab is being used concurrently with glucocorticoids.

- Documentation the patient will be receiving PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) during treatment or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the patient is 18 years of age or older, and the request is for any medication other than Ruxience (rituximab-pvvr) Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- Documentation the patient will continue to receive PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Rituximab is being prescribed at an FDA approved dose.

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)

Initial Authorization:

- Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.
- Patient meets one of the following:
    - Bohan and Peter score indicating definite DM or PM
    - Bohan and Peter score indicating probable DM or PM AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist)
- Patient does NOT have cancer associated myositis defined as myositis within 2 years of cancer diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cured)
- One of the following:
    - Patient has a documented trial and failure of, or has a documented medical reason for not using methotrexate (MTX) OR azathioprine
    - Patient has severe, life-threatening weakness or dysphagia
- Rituximab is prescribed at a dose per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I or IIa recommendation).
- If the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- Rituximab is prescribed at a medically accepted dose per the medical compendia.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

OTHER MEDICALLY ACCEPTED INDICATIONS

Initial Authorization:

- The medication is prescribed for a non-FDA approved indication but is considered to be a medically accepted use of the medication per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I or Iia recommendation.
- The medication is prescribed at a medically accepted dose per the medical compendia as defined above.
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Documentation was submitted indicating that the member has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses of medications) of ALL first line medical therapies as recommended by the medical compendia and standard care guidelines and/or has another documented medical reason (e.g. intolerance, contraindications, etc.) for not receiving or trying all first line medical treatment(s).
- If the request is for any medication other than Ruxience (rituximab-pvvr), there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 3 month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- The medication is prescribed at a medically accepted dose per the medical compendia
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation from medical chart was submitted indicating that the member has significantly clinically benefited from the medication.

If all of the above conditions are met, the request will be approved for up to a 3 month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: 11/2025

Title: Rozanolixizumab-noli (Rystiggo)

MEDICALLY NECESSARY

ROZANOLIXIZUMAB-NOLI (RYSTIGGO)

Rozanolixizumab-noli (Rystiggo) is considered medically necessary and, therefore, covered for the treatment of adult individuals 18 years of age or older with generalized myasthenia gravis (gMG), when all of the following criteria are met, including dosing and frequency:

Initial Criteria

- The individual has documented diagnosis of gMG based individual's history and supported by previous evaluations
- The individual has a confirmed positive record of autoantibodies against acetylcholine receptor (AChR) or muscle-specific kinase (MuSK) .
- The individual has Myasthenia Gravis Foundation of America (MGFA) Class II, III, IVa
- The individual has Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of at least 3 (with ≥3 points from non-ocular symptom) AND a quantitative myasthenia gravis (QMG) score of at least 11
- The individual has a history of inadequate response or intolerance one of the following :
    - standard-of-care therapy (i.e, acetylcholinesterase inhibitors [AChEIs] e.g., pyridostigmine or corticosteroids e.g.,prednisone)
    - use of immunoglobulin g (IVIg)/ plasma exchange (PLEX) as rescue therapy

- The individual is not receiving rozanolixizumab-noli (Rystiggo) in combination with a complement inhibitor (e.g. eculizumab (Soliris),ravulizumab (Ultomiris), etc.) or another neonatal Fc receptor blocker (e.g.efgartigimod alfa-fcab (Vyvgart))
- Dosing and frequency for rozanolixizumab-noli (Rystiggo) is based on a body weight (BW) of the individual, once weekly for six weeks with every next cycle initiated not sooner than 63 days from the start of the previous treatment cycle:
    - if (BW) less than 50 kg: 420 mg
    - if (BW) 50 kg to less than 100 kg 560 mg
    - if (BW) 100 kg and above 840 mg

Continuation Criteria

Submission of medical records to demonstrate a positive clinical response from baseline (e.g., two-point reduction in MG-ADL total score). The safety of initiating subsequent cycles sooner than 63 days from the start of the previous treatment cycle has not been established.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Sebelipase alfa (Kanuma®)

MEDICALLY NECESSARY

INFANTS WITH RAPIDLY PROGRESSIVE LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY PRESENTING WITHIN THE FIRST 6 MONTHS OF LIFE
Sebelipase alfa (Kanuma) is considered medically necessary and, therefore, covered for infants with rapidly progressive lysosomal acid lipase (LAL) deficiency presenting within the first 6 months of life when **all** the following criteria, including Dosing and Frequency Requirements, are met:

- Diagnosis of LAL deficiency is confirmed by **either** of the following:
    - Confirmation of the absence or deficiency of LAL resulting from dried blood spot (DBS) testing
    - Confirmation of molecular genetic testing that reveals pathogenic variation(s) in the lipase A, lysosomal acid type (LIPA) gene, which results in reduction of functionality of LAL enzyme activity
- Documented presence of clinical signs and symptoms of the disease (e.g., diarrhea, vomiting, marked failure to thrive [e.g., weight decreasing across two or more major centiles on a standard World Health Organization {WHO} weight-for-age {WFA} chart; body weight below the 10th centile on a standard WHO WFA chart and no weight gain during the 2 weeks before screening; loss of greater than 5 percent of birth weight after 2 weeks of age], abdominal distension, hepatomegaly, splenomegaly, rapidly progressive liver failure, adrenal calcifications, anemia)

Dosing and Frequency Requirements

The following dosing and frequency information, and definitions of suboptimal clinical responses, were taken from the Prescribing Information for this product and specific reliable evidence including peer-reviewed literature:

Infants with rapidly progressive LAL deficiency presenting within the first six months of life: 1 mg/kg intravenously (IV) once weekly. If optimal clinical response is not achieved, increase to 3 mg/kg once weekly. For continued suboptimal clinical response on 3 mg/kg once weekly dosage, further increase the dosage to 5 mg/kg once weekly.

A suboptimal clinical response within the first 3 months of treatment is defined as **all** of the following:

- Absence of other potential causes of any observed clinical manifestations

- Absence of missed infusions
- Absence of acute cholecystitis
- Absence of the initiation of a potentially hepatotoxic concomitant medication

- Absence of a concomitant illness that could cause any of the observed lack of clinical responsiveness to the drug
- **Two or more** of the following after receiving at least 4 infusions of the current dose:
    - Poor growth (i.e., failure to gain an average of 5 g/kg body weight per day **AND** the presence of either WHO weight-for-length or weight-for-height z score less than -2, or WHO length-for-age or height-for-age z score less than -2)
    - Albumin less than 3.5 g/dl
    - ALT more than twice the upper limit of normal (ULN)
    - Ongoing requirement for blood and/or platelet transfusion
    - Presence of anti-drug, anti-enzyme, or anti-uptake antibodies

A suboptimal clinical response after the first 3 months of treatment is defined as lack of improvement from a minimum of 3 assessments or failure to normalize within 12 months of treatment in **all** of the following:

- Absence of other potential causes of any observed clinical manifestations
- Absence of missed infusions
- Absence of acute cholecystitis
- Absence of the initiation of a potentially hepatotoxic concomitant medication
- Absence of a concomitant illness that could cause any of the observed lack of clinical responsiveness to the drug
- **One or more** of the following (not an all-inclusive list of the clinically important manifestations of LAL deficiency):
    - Decrease in weight-for-age crossing at least 2 major centiles
    - Albumin less than 3.5 g/dl

- ALT more than twice the ULN
- Persistent or worsening hepatomegaly, splenomegaly, or lymphadenopathy
- Presence of anti-drug, anti-enzyme, or anti-uptake antibodies

PEDIATRIC AND ADULT INDIVIDUALS WITH LAL DEFICIENCY

Initial Therapy

Sebelipase alfa (Kanuma) is considered medically necessary and, therefore, covered for pediatric and adult individuals with lysosomal acid lipase (LAL) deficiency when **all** the following criteria, including Dosing and Frequency Requirements, are met:

- Diagnosis of LAL deficiency is confirmed by **either** of the following:
  - Confirmation of the absence or deficiency of LAL resulting from dried blood spot (DBS) testing
  - Confirmation of molecular genetic testing that reveals pathogenic variation(s) in the lipase A, lysosomal acid type (LIPA) gene, which results in reduction of functionality of LAL enzyme activity
- Documented presence of clinical signs and symptoms of the disease (e.g., hepatomegaly, dyslipidemia, increased serum transaminases [ALT, aspartate aminotransferase {AST}], evidence of advanced liver disease [i.e., cirrhosis, fibrosis, steatosis], histologically-confirmed disease recurrence in individuals with past liver or hematopoietic transplant more than 2 years prior)

Continuation Therapy

Sebelipase alfa (Kanuma) is considered medically necessary and, therefore, covered for continuation therapy of LAL deficiency in individuals who have improvement from baseline (for the initial request for continuation therapy), or maintenance of previous improvements, as evidenced by at least **two** of the following:

- Improvement in any **one** of the following symptoms:
  - For pediatric individuals: increase in growth and/or weight parameters (based on expected anthropometric parameters)
  - Decrease in diarrhea/vomiting (i.e., decrease in frequency and/or volume)

    - Improvement in liver volume (normal liver volume in liters is defined as 2.5 percent of body weight in kg)
    - Improvement in liver fat content (i.e., decrease of >5 percent in the liver fat content from baseline as measured by magnetic resonance imaging [MRI]; the normal fat content of the liver is considered to be <5 percent)
    - Improvement in liver histopathology (e.g., cirrhosis, fibrosis)
- Improvement in any **one** component of a lipid panels:
    - Improvement in low-density lipoprotein-cholesterol (LDL-c) (based on clinical comparisons with baseline and/or previous results)
    - Improvement in high-density lipoprotein-cholesterol (HDL-c) (based on clinical comparisons with baseline and/or previous results)
    - Improvement in triglycerides (TG) (based on clinical comparisons with baseline and/or previous results)
- Improvement in any **one** serum transaminases
    - Improvement in ALT (based on clinical comparisons with baseline and/or previous results)
    - Improvement in AST (based on clinical comparisons with baseline and/or previous results)

If the individual does not demonstrate continued improvement, or maintenance of previous improvement, from baseline in **two** of the above after 8 consecutive infusions, and is on a higher dosage of sebelipase alfa (Kanuma), then the dosage will be decreased to the previous dosage that demonstrated a level of efficacy for the individual.

Dosing and Frequency Requirements

The following dosing and frequency information, and definitions of suboptimal clinical response/significant clinical progression, were taken from the Prescribing Information for this product and specific reliable evidence including peer-reviewed literature:

Pediatric and Adult Individuals with LAL Deficiency: 1 mg/kg IV once every other week. For individuals with a suboptimal clinical response or significant clinical progression, increase the dosage to 3 mg/kg once every other week.

A suboptimal clinical response is defined as **all** of the following after at least 8 consecutive infusions:

- Absence of other potential causes of any observed clinical manifestations (e.g., initiation of a potentially hepatotoxic concomitant medication in an individual with abnormal AST or ALT; missed infusions; development of viral or autoimmune hepatitis; development of another alternative etiology of liver disease)
- Presence of **one** of the following:
    - ALT or AST remain abnormal and either have not improved from baseline or have worsened from the previously achieved lowest value over the preceding 8 consecutive infusions
    - LDL-c or TG remain abnormal and either have not improved or have worsened over the preceding 8 consecutive infusions
    - The individual is <18 years of age at the time of the assessment and has a WFA z-score that is 2 standard deviations below the mean and either did not improve or worsened during the preceding 6 months and the individual did not miss more than 20 percent of infusions in the preceding 6 months

A significant clinical progression is defined as **all** of the following after at least 5 consecutive infusions:

- Absence of other potential causes of any observed clinical manifestations (e.g., initiation of a potentially hepatotoxic concomitant medication in an individual with abnormal AST or ALT; missed infusions; development of viral or autoimmune hepatitis; development of another alternative etiology of liver disease)
- Confirmed elevation of ALT or AST to >5x ULN and at least twice the highest pre-treatment value **AND** the presence of **one** of the following:
    - Increase of total bilirubin to >3x ULN and at least twice the highest pre-treatment value
    - Prolongation of prothrombin time (PT) 4 seconds or greater above baseline
    - Development or worsening of ascites
    - Development of encephalopathy

Subject to the terms and conditions of the applicable benefit contract, sebelipase alfa (Kanuma) is covered under the medical benefits of the Company's products when the medical necessity criteria and Dosing and Frequency Requirements listed in this medical policy are met.

The Company reserves the right to modify the Dosing and Frequency Requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of

sebelipase alfa (Kanuma). Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to: the US Food and Drug Administration (FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of sebelipase alfa (Kanuma) outside of the Dosing and Frequency Requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on Off-Label Coverage for Prescription Drugs and/or Biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the utilization management activities. The Company reserves the right to conduct post-payment review and audit procedures for any claims submitted for sebelipase alfa (Kanuma).

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Secukinumab (Cosentyx®) for Intravenous Use

MEDICALLY NECESSARY

INITIAL THERAPY
Secukinumab (Cosentyx) for intravenous (IV) infusion is considered medically necessary and, therefore, covered for the following indications when, for each individual indication, all of the associated criteria are met:

Note: *Secukinumab (Cosentyx) for IV infusion is only eligible for coverage when the individual has a documented contraindication, intolerance to or there is a clinical reason that a trial of Secukinumab (Cosentyx) for subcutaneous (SC) injection would be otherwise inappropriate for the member.*

Psoriatic Arthritis (PsA)
Secukinumab (Cosentyx) for IV infusion may be covered as monotherapy or concomitantly with non-biologic DMARDs when **all** of the following inclusion criteria are met:

- The individual is 18 years of age or older.
- The individual has had an inadequate response after at least 3 months of one or more DMARDs (e.g., methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine), or the use of all DMARDs is contraindicated in the individual.
- The individual has a documented failure, contraindication, or intolerance to **one** anti-TNF such as infliximab (Remicade) **or** golimumab (Simponi Aria), unless there is a medical reason why an anti-TNF agent cannot be tried.
- Active or latent tuberculosis (TB) has been ruled out.
- Secukinumab (Cosentyx) will not be used in combination with other biologic DMARDs or Janus kinase inhibitor (JAK) inhibitors.

Ankylosing Spondylitis (AS)

- The individual is at least 18 years old.
- Documentation of failure, contraindication, or intolerance to the following:
    - At least a 4-week trial of two nonsteroidal anti-inflammatory drugs (NSAIDs) at maximum recommended or tolerated anti-inflammatory dose

- The individual has a documented failure, contraindication, or intolerance to **one** anti-TNF such as infliximab (Remicade) **or** golimumab (Simponi Aria), unless there is a medical reason why an anti-TNF agent cannot be tried.

- Active or latent TB has been ruled out.

Axial spondyloarthritis (nonradiographic):

- When all of the following criteria are met:
    - The individual is over 18 years of age with evidence of active disease (increasing inflammation, pain, disability, and decreased function)
    - Documentation of an adequate therapeutic trial* of at least two NSAIDs that have failed to control symptoms

*An adequate therapeutic trial is defined as: Treatment with NSAIDs for at least 3 months at maximum recommended or tolerated anti-inflammatory dose unless treatment is discontinued due to lack of response, intolerance, toxicity or contraindication.

- Individual has a documented failure, contraindication, or intolerance to TWO anti-TNF's such as infliximab (Remicade) AND golimumab (Simponi Aria), unless there was a primary non-response of an anti-TNF or a serious adverse event associated with an anti-TNF (in which case no additional anti-TNF trial is needed).

- If the above criteria are not met, there must be documentation both of very severe disease and that the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform activities of daily living [ADLs], or severe impact on quality of life)
- Active or latent tuberculosis (TB) has been ruled out.

**Primary non-response: Lack of response within the first 6 months of treatment. Secondary non-response: Loss of response after having sustained a positive effectiveness outcome for ≥12 months from treatment initiation, or after two consecutive positive measurements with a minimum time interval.*

CONTINUATION THERAPY
Secukinumab (Cosentyx) for IV infusion is considered medically necessary and, therefore, covered for continuation therapy when the individual meets all of the following:

- There is documentation of a positive clinical response or stabilization to therapy (e.g., improvement in total active [swollen and tender] joint count from baseline, improvement in symptoms [e.g., pain, stiffness, inflammation, fever, fatigue, nonproductive cough] from baseline)

EXPERIMENTAL/INVESTIGATIONAL

All other uses for secukinumab (Cosentyx) for IV use are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Self-Administered Drugs and Biologics

Policy

Coverage is subject to the terms, conditions, and limitations of the member's contract.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

For most of the Company's commercial products, self-administered drugs and biologics are not covered under the member's medical benefit and, therefore, are not eligible for reimbursement under the member's medical benefit. Coverage may be available under the pharmacy benefit or through a pharmacy vendor. Individual benefits must be verified.

The codes listed in Attachment A of this policy represent the products that the Company considers to meet the definition of self-administered drugs and biologics. These drugs are not eligible for reimbursement consideration under the member's medical benefit even if the drugs are provided or administered by a professional provider (for some products, there may be exceptions relating to coagulation factors for hemophilia and other bleeding conditions [please refer to the medical policy titled "Coagulation Factors", policy number 08.00.92]). Additionally, drugs may be considered self-administered by the Company even in circumstances where initial medical supervision and/or instruction is required prior to patient self-administration.

The self-administered designation does not apply to prescription drugs and biologics that are: (a) mandated to be covered by law under the medical benefit (e.g., insulin or any drug required for the treatment of diabetes); or (b) required for treatment of an emergency condition that requires the use of a Company-determined self-administered drug (e.g., epinephrine).

When the member or caregiver is unable to administer a self-administered drug, the drug can be administered by an eligible professional provider (e.g., a professional provider may administer the drug when a caregiver is unable to provide treatment due to a prolonged trip or absence). In this situation, the drug remains ineligible for coverage under the medical benefit; however, the administration fee for the professional provider is covered and eligible for reimbursement under the member's medical benefit.

Injection therapy services (represented by "S" codes listed in the coding table of this policy) must not be utilized by the eligible professional provider when reporting the administration of a self-administered drug because these services encompass more than the administration of the drug (e.g., pharmacy services, care coordination). Therefore, they are not covered and not eligible for reimbursement under the medical benefit of the Company. Coverage may be available under the pharmacy benefit or through a pharmacy vendor. For members enrolled in

commercial plans in New Jersey, self-administered coagulation factors may be available under the applicable medical or pharmacy benefit. Individual benefits must be verified.

MAINTENANCE OF DRUG/BIOLOGICS LIST

The drugs and biologics listed in Attachment A of this policy are considered by the Company to be self-administered and are subject to change as new medications come to market or new determinations are made by the Company.

BILLING REQUIREMENTS

For drugs and biologics that have more than one method of administration, application of an appropriate modifier is required to indicate the route of administration.

- To report the subcutaneous route of administration, append the following modifier: JB Administered Subcutaneously

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, utilization management/referral requirements, provider contracts, and Company policies apply.

Duration of authorization: 12 months

Version Effective Date: 01/01/2025

Attachment A: Self-Administered Drugs and Biologics
Description: Prescription drugs and biologics that are considered by the Company to be self-administered.

Policy Attachment

Attachment to Policy #08.00.78at

Attachment: A

Policy #: 08.00.78at

Description: Prescription drugs and biologics that are considered by the Company to be self-administered.

Title: Self-Administered Drugs and Biologics

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

Self-Administered Drugs and Biologics

For most of the Company's commercial products, self-administered drugs and biologics are not covered under the member's medical benefit and, therefore, are not eligible for reimbursement under the member's medical benefit. Self-administered drugs are only covered under the member's pharmacy benefit, if one exists, unless an exception by product or group exists. Therefore, individual benefits must be verified, as coverage may vary by product and/or group. Providers should work directly with the member's Pharmacy Benefit Administrator on options to obtain a self-administered drug through specialty pharmacy distribution under the member's pharmacy benefit.

The Company-determined, self-administered drugs and biologics listed in this Attachment are subject to change as new medications come to market or new determinations are made by the Company. This list contains only those drugs and biologics that are determined by the Company to be self-administered. Any FDA-approved biosimilar products will be managed the same way as their reference product, already listed in this Table.

Note: Drug/Biologic codes that must use modifier JB when the subcutaneous form of the drug/biologic is administered are listed with an asterisk * in this Coding Table.

Brand Name	Generic Name	USC Class	Code	Date Drug or Biologic Classifi

				ed as Self-Administered
N/A	concizumab	Coagulants, Other	J3590	Upon FDA-approval
N/A	dihydroergotamine (DHE) (prefilled autoinject or for self-administered administration)	Anti-Migraine, Other	J3490	Upon FDA-approval
N/A	garadacimab	Clotting Factor inhibitor	J3590	Upon FDA-approval
N/A	glepaglutide	Gastrointestinal	J3590	Upon FDA-approval
N/A	naloxone hydrochloride	Opioid antagonist	J2310	10/05/2020
N/A	volanesorsen sodium	Antihyperlipidemia Agents	J3490	01/01/2019
Abrilada	adalimumab-afzb	Antiarthritic, Syst. Bio. Response Modifier	Q5145	10/21/2019
Actemra *(for subcutaneous use)* *Note: For Intravenous use of Actemra covered under the medical benefit, please refer to policy 08.00.85 Tocilizumab (Actemra®) and related biosimilars for Intravenous Infusion*	tocilizumab	Monoclonal Antibodies	J3590	10/22/2013
Actimmune	interferon gamma–1b	Interferons	J9216	1/1/2010

Adbry	tralokinumab-ldrm	Monoclonal Antibodies	J3590	06/07/2021
Advate	antihemophilic factor VIII	Clotting Factor	J7192	1/1/2014
Adynovate	antihemophilic factor VIII	Clotting Factor	J7207	1/01/2016
Afstyla	antihemophilic factor VIII	Factor VIII	J7210	12/12/2016
Aimovig	erenumab-aooe	Monoclonal Antibodies	J3590	05/28/2018
Ajovy	fremanezumab-vfrm	Monoclonal Antibodies	J3031 J3590	01/01/2019
Alphanate	antihemophilic factor VIII/von Willebrand factor complex (human)	Clotting Factor	J7186	1/1/2014
Alphanine SD	coagulation factor IX (human)	Clotting Factor	J7193	1/1/2014
Alprolix	coagulation factor IX (recombinant)	Clotting Factor	J7201	7/30/2014
Altuviiio	antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl	Clotting Factor VIII	J7214	02/23/2023
Amjevita	adalimumab-atto	Antiarthritic, Syst. Bio. Response Modifier	J3590	12/12/2016
Apokyn	apomorphine	Anti-Parkinson's, Others	J0364	1/1/2010

Arcalyst	rilonacept	Immunomodulators	J2793	01/01/2019
Arixtra	fondaparinux	Anticoagulants, Injectable, Other	J1652	1/1/2010
Avonex	interferon beta–1a	Interferons	J1826	1/1/2011
Benefix	coagulation factor IX (recombinant)	Clotting Factor	J7195	1/1/2014
Benlysta* *(for subcutaneous use)* *Note: For Intravenous use of Benlysta covered under the medical benefit, please refer to policy 08.00.99 Belimumab (Benlysta®)*	belimumab	Monoclonal Antibodies	J3590	09/28/2017
Berinert	C1 Esterase Inhibitor Subcutaneous (Human)	Biologicals, Other	J0597	01/01/2018
Besremi	ropeginterferon alfa-2b	Interferons	J3490	06/07/2021
Betaseron	interferon beta–1b	Interferons	J1830 J3490	1/1/2010
Bimzelx	bimekizumab-bkzx	Monoclonal Antibodies	J3590	10/17/2023
Bonsity	teriparatide	Bone Formation Agents	J3590	10/05/2020
Bravelle	urofollitropin	Gonadotropins	J3355	1/1/2010
Cablivi *(for subcutaneous use)*	caplacizumab-yhdp	Platelet Inhibitors, Other	J3590	10/21/2019

Caverject	alprostadil	Peripheral Vasodilators	J0270 J3490	1/1/2010
Cetrotide	cetrorelix acetate	Anabolic Hormones	J3490	1/1/2010
Cimzia	certolizumab pegol	Gastrointes-tinal anti-Inflammatory	J0717 J3590	1/1/2014
Cinryze	C1 Esterase Inhibitor Subcutaneous (Human)	Biologicals, Other	J0598	01/01/2018
Coagadex	coagulation factor X, (human)	Clotting Factor	J7175	1/01/2016
Copaxone	glatiramer acetate	Nervous System Disorders, Other	J1595	1/1/2010
Corifact	Factor XIIIf concentrate (Human)	Clotting Factor	J7180	12/01/2014
Cosentyx *(for subcutaneous use)*	secukinumab	Monoclonal Antibodies	J3590	03/25/2015
Cyltezo	adalimumab-adbm	Antiarthritic, Syst. Bio. Response Modifier	Q5143	05/28/2018
Dupixent	dupilumab	Monoclonal Antibodies	J3590	05/31/2017
Ebglyss	lebrikizumab-lbkz	Monoclonal Antibodies	J3590	09/13/2024
Edex	alprostadil	Peripheral Vasodilators	J0270 J3490	1/1/2010

Egrifta SV	tesamorelin	Analog; growth hormone-releasing factor	J3490	01/01/2021
Eloctate	recombinant factor VIII Fc fusion protein	Clotting Factor	J7205	7/30/2014
Elonva	corifollitropin alfa	Modified follicule stimulating hormone	J3490	7/30/2014
Emgality	galcanezumab-gnlm	Monoclonal Antibodies	J3590	05/28/2018
Empaveli	pegcetacoplan	Hemolysis reduction	J3490	06/07/2021
Enbrel	etanercept	Antiarthritic, Syst. Bio. Response Modifier	J1438 J3590	1/1/2010
Enspryng	satralizumab	Monoclonal Antibodies	J3590	10/05/2020
Entyvio *(for subcutaneous use)* *Note: For Intravenous use of Entyvio covered under the medical benefit, please refer* *to policy 08.01.18 Vedolizumab (Entyvio®)*	vedolizumab	Monoclonal Antibodies	J3590	10/05/2020
Erelzi	etanercept-szzs	Antiarthritic, Syst. Bio. Response Modifier	J3590	12/12/2016
Esperoct	antihemophilic factor (recombinant), glycopegylated-exei	Clotting Factor	J7204	7/1/2020

Eticovo	etanercept-ykro	Antiarthritic, Syst. Bio. Response Modifier	J3590	10/21/2019
Extavia	interferon beta–1b	Interferons	J1830 J3490	1/1/2010
Feiba	anti-inhibitor coagulant complex	Hemostatic	J7198	1/1/2014
Fasenra	benralizumab	Monoclonal Antibodies	J0517	01/01/2021
Fibryga	fibrinogen concentrate (human)	Clotting Factor	J7177	09/28/2017
Firazyr	icatibant	Bradykinin B2 receptor antagonist	J1744	9/9/2011
Follistim AQ	follitropin beta	Gonadotropins	S0128	1/1/2010
Forteo	teriparatide	Bone Formation Agents	J3110	1/1/2010
Fragmin	dalteparin	Anticoagulants, Fractionated Heparins	J1645	1/1/2010
Furoscix *(for subcutaneous use)*	furosemide	Diuretics, Loop	J1941	10/07/2022
Fuzeon	enfuvirtide	HIV Entry/Fusion Inhibitor	J1324	1/1/2010
Ganirelix	ganirelix acetate	Gonadotropins	S0132	1/1/2010
Gattex	teduglutide	GLP Agonist	J3490	9/12/2012
Genotropin	somatropin	Anabolic Hormones	J2941	1/1/2010
Genotropin MiniQuick	somatropin	Anabolic Hormones	J2941	1/1/2010

Glatopa	glatiramer acetate	Nervous System Disorders, Other	J1595	1/01/2016
Gonal-f	follitropin alfa	Gonadotropins	S0126	1/1/2010
Gonal-f RFF	follitropin alfa	Gonadotropins	S0126	1/1/2010
Hadlima	adalimumab-bwwd	Antiarthritic, Syst. Bio. Response Modifier	J3590	10/21/2019
Haegarda	C1 Esterase Inhibitor Subcutaneous (Human)	Biologicals, Other	J0599	09/28/2017
Hemlibra	emicizumab-kxwh	Clotting Factor; Monoclonal Antibodies	J7170	05/28/2018
Hemofil-M	antihemophilic factor VIII	Clotting Factor	J7190	1/1/2014
Hepcludex	bulevirtide	Viral hepatitis products	J3490	Upon FDA-approval
Hulio	adalimumab-fkip	Antiarthritic, Syst. Bio. Response Modifier	Q5140	10/05/2020
Humate-P	antihemophilic factor VIII/Von Willebrand factor complex (human)	Clotting Factor	J7187	1/1/2014
Humatrope	somatropin	Anabolic Hormones	J2941	1/1/2010
Humira	adalimumab	Antiarthritic, Syst. Bio. Response Modifier	J0139	1/1/2010
Hympavzi	marstacimab-hncq	Clotting Factor; Monoclonal Antibodies	J3590	10/11/2024

Hyrimoz	adalimumab-adaz	Antiarthritic, Syst. Bio. Response Modifier	J3590	10/21/2019
Idacio	adalimumab-aacf	Antiarthritic, Syst. Bio. Response Modifier	Q5144	12/13/2022
Idelvion	coagulation Factor IX (recombinant)	Factor IX	J7202	3/09/2016
Imcivree	setmelanotide	Anti-obesity in rare disease	J3490	01/01/2021
Imitrex	sumatriptan	Serotonin 5HT-1 Receptor Agonists	J3030 J3490	1/1/2010
Increlex	mecasermin	Anabolic Hormones	J2170	1/1/2010
Infergen	interferon alfacon–1	Interferons	J9212	1/1/2010
Innohep	tinzaparin	Anticoagulants, Fractionated Heparins	J1655	1/1/2010
Ixinity	coagulation Factor IX (recombinant)	Factor IX	J7213	7/15/2015
Jivi	antihemophilic Factor VIII	Clotting Factor	J7208	01/01/2019
Kesimpta	ofatumumab	Monoclonal Antibodies	J3590	10/05/2020
Kevzara	sarilumab	Monoclonal Antibodies	J3590	12/12/2016
Kineret	anakinra	Antiarthritic, Syst.Bio. Response Modifier	J3490	1/1/2010
Koate-DVI	antihemophilic Factor VIII	Clotting Factor	J7190	1/1/2014

Kogenate FS	antihemophilic Factor VIII	Clotting Factor	J7192	1/1/2014
Kovaltry	antihemophilic Factor VIII	Clotting Factor	J7211	3/09/2016
Lovenox	enoxaparin	Anticoagulants, Fractionated Heparins	J1650	1/1/2010
Lupron *(2-week kit only)*	leuprolide	GRH Analogs	J9218	1/1/2010
Menopur	menotropins	Gonadotropins	S0122	1/1/2010
Miacalcin	calcitonin–salmon	Bone Density Regulators, Calcitonins	J0630	1/1/2010
Mononine	Coagulation Factor IX (human)	Clotting Factor	J7193	1/1/2014
Myalept	metreleptin	Leptin Analog	J3590	7/30/2014
Natpara	recombinant human parathyroid hormone (rhPTH 1-84)	Hormone	J3590	12/01/2014
Nemluvio	nemolizumab-ilto	Dermatologicals	J3590	08/12/2024
Ngenla	somatrogon-ghla	Anabolic Hormones	J2941	06/07/2021
Norditropin	somatropin	Anabolic Hormones	J2941	1/1/2010
Norditropin NordiFlex	somatropin	Anabolic Hormones	J2941	1/1/2010
Novarel	chorionic gonadotropin	Gonadotropins	J0725	1/1/2010
Novoeight	turotocog alfa	Clotting Factor	J7182	10/16/2013

NovosevenRT	recombinant Coagulation Factor VIIa (rFVIIa)	Clotting Factor	J7189	1/1/2014
Nucala	mepolizumab	Monoclonal Antibodies	J2182	01/01/2021
Nulibry	fosdenopterin	Nervous system disorders, Other	J3590	01/01/2021
Nutropin	somatropin	Anabolic Hormones	J2941	1/1/2010
Nutropin AQ	somatropin	Anabolic Hormones	J2941	1/1/2010
Nuwiq	Antihemophilic Factor VIII	Clotting Factor	J7209	1/01/2016
Obizur	recombinant antihemophilic porcine sequence factor VIII	Clotting Factor	J7188	12/01/2014
Oclaiz	octreotide	somatostatin analog	J3490	Upon FDA-approval
Omnitrope	somatropin	Anabolic Hormones	J2941	1/1/2010
Omvoh *(for subcutaneous use)*	mirikizumab-mrkz	Monoclonal Antibodies	J2267	10/26/2023
Orencia* *(for subcutaneous use)* *Note: for Intravenous use of Orencia covered under the medical benefit, please refer to policy 08.00.62 Abatacept (Orencia®)*	abatacept	Immunomodulators	J3590	9/9/2011
Otrexup	methotrexate	Folic Acid Antagonist	J3490	10/11/2013
Ovidrel	chorionic gonadotropin	Gonadotropins	J0725	1/1/2010

Palynziq	pegvaliase-pqpz	Enzymes, Systemic	J3590	05/28/2018
Pegasys	peginterferon alfa–2a	Interferons	S0145	1/1/2010
PEG-Intron	peginterferon alfa–2b	Interferons	S0148	10/1/2010
PEG-Intron Redi-Pen	peginterferon alfa–2b	Interferons	S0148	10/1/2010
Plegridy	PEG interferon beta-1A	Interferons	J3490	7/30/2014
Praluent	alriocumab	Monoclonal Antibodies	J3590	7/15/2015
Pregnyl	chorionic gonadotropin	Gonadotropins	J0725	1/1/2010
Profilnine	coagulation Factor IX complex (human)	Clotting Factor	J7194	10/25/2021
Proplex T	coagulation Factor IX complex (human)	Clotting Factor	J7194	1/1/2014
Protropin	somatrem	Anabolic Hormones	J2940	4/30/2010
Rasuvo	methotrexate	folic acid antagonist	J3490	7/30/2014
Rebif	interferon beta–1a	Interferons	J1826	1/1/2011
Rebif	interferon beta–1a	Interferons	Q3027	1/1/2014
Rebif	interferon beta–1a	Interferons	Q3028	1/1/2014
Rebinyn	coagulation Factor IX (recombinant)	Clotting Factor	J7203	09/28/2017
Recombinate	antihemophilic Factor VIII	Clotting Factor	J7192	1/1/2014

RediTrex	methotrexate	Folic acid antagonist	J3490	10/05/2020
Relistor	methylnaltrexone bromide acetate	MU-Opioid Receptor Antagonists	J2212	1/1/2010
Repatha	evolocumab	Monoclonal Antibodies	J3590	7/15/2015
Repronex	menotropins	Gonadotropins	S0122	1/1/2010
RiaSTAP	fibrinogen concentrate (human)	Clotting Factor	J7178	3/09/2016
Rivfloza	nedosiran	Genitourinary Tract, Other	J3590	09/29/2023
Rixubis	coagulation Factor IX (recombinant)	Clotting Factor	J7200	1/1/2014
Roferon-A	interferon alfa-2a	Interferons	J9213	4/30/2010
Ruconest	C1 Esterase Inhibitor Subcutaneous (Recombinant)	Biologicals, Other	J0596	01/01/2018
Saizen	somatropin	Anabolic Hormones	J2941	1/1/2010
Saxenda	liraglutide	Human GLP-1 Analogs	J3490	1/01/2016
Serostim	somatropin	Anabolic Hormones	J2941	1/1/2010
Sevenfact	coagulation factor VIIa (recombinant)-jncw	Clotting Factor	J7212	10/05/2020
Signifor	pasireotide	somatostatin analog	J3490	1/31/2013
Siliq	brodalumab	Monoclonal Antibodies	J3590	12/12/2016

Simponi	golimumab	Antiarthritic, Syst.Bio. Response Modifier	J3490	1/1/2010
Skyrizi* *(for subcutaneous use)* *Note: for Intravenous use of Skyrizi covered under the medical benefit, please refer to policy 08.01.95 Risankizumab-rzaa (Skyrizi®) for Intravenous Use*	risankizumab-rzaa	Monoclonal Antibodies	J3590	10/21/2019
Simlandi	adalimumab-ryvk	Antiarthritic, Syst. Bio. Response Modifier	Q5142	02/23/2024
Sogroya	somapacitan-beco	Analog; growth hormone	J3590	01/01/2021
Somavert	pegvisomant	Anabolic Hormones	J3490	1/1/2010
Skytrofa	lonapegsomatropin-tcgd	Anabolic Hormones	J3490	06/07/2021
Strensiq	asfotase alfa	Enzymes, Systemic	J3490	3/25/2015
Sumavel DosePro	sumatriptan	Serotonin 5HT-1 Receptor Agonists	J3030 J3490	1/1/2010
Supprelin	histrelin	Sex Hormones, Other	J1675	1/1/2010
Sylatron	peginterferon alfa–2b	Interferons	S0148	5/10/2011
Takhzyro	lanadelumab-flyo	Monoclonal Antibodies	J0593 J3590	01/01/2019

Taltz	ixekizumab	Monoclonal Antibodies	J3590	12/12/2016
Tegsedi	inotersen	Neuropathic Pain, Other	J3490	01/01/2019
Tev-Tropin	somatropin	Anabolic Hormones	J2941	1/1/2010
Tezspire *(for subcutaneous use)*	tezepelumab-ekko	Respiratory Other	J2356	01/01/2024
Tremfya *(for subcutaneous use)*	guselkumab	Monoclonal Antibodies	J1628	09/28/2017
Tretten	coagulation Factor XIII-A-subunit (recombinant)	Coagulation Factor	J7181	12/23/2013
Tyenne *(for subcutaneous use)*	tocilizumab-aazg	Monoclonal Antibodies	Q5135	03/05/2024
Tymlos	abaloparatide	Bone Formation Agents	J3490	05/31/2017
Tyvaso DPI (inhalation powder, for oral inhalation use)	treprostinil	Prostacyclin Mimetic	J3490	05/23/2022
Ultomiris* *(for subcutaneous use)* *Note: for Intravenous use of Ultomiris covered under the medical benefit, please refer to policy 08.00.84 Eculizumab (Soliris®) and Related Biosimilars, Ravulizumab-cwvz (Ultomiris®) for intravenous use*	ravulizumab-cwvz	Paroxysmal Nocturnal Hemoglobinuria and Atypical Hemolytic Uremic Syndrome	J3590	07/22/2022
Vonvendi	Von Willebrand Factor (recombinant)	Coagulation Factor	J7179	3/09/2016

Voxzogo	vosoritide	Bone growth disorder	J3490	06/07/2021
Vyleesi	bremelanotide	Sexual Function Disorders	J3490	10/21/2019
Wainua	eplontersen	Neuropathic Pain, Other	J3490	12/21/2023
Wegovy	semaglutide	Anti-Obesity	J3490	06/04/2021
Wilate	Von Willebrand Factor/Factor VIII Complex (human)	Coagulation Factor Complex	J7183	1/1/2014
Winrevair	sotatercept-csrk	Cardiac agents, others	J3590	03/26/2024
Xolair (prefilled syringe for self-administered administration) *Note: For administration by a professional provider, covered under the medical benefit, please refer to policy 08.00.55 Omalizumab (Xolair®)*	omalizumab	Respiratory, Other	J3590	04/09/2021
Xyntha	antihemophilic Factor (recombinant)	Clotting Factor	J7185	1/1/2014
Xyosted	testosterone enanthate	Sex Hormones, Other	J3121	05/28/2018
Yorvipath	palopegteriparatide	Parathyroid agent	J3490	08/09/2024
Yuflyma	adalimumab-aaty	Antiarthritic, Syst. Bio. Response Modifier	Q5141	05/24/2023

Yusimry	adalimumab-aqvh	Antiarthritic, Syst. Bio. Response Modifier	J3590	12/17/2021
Zegalogue	dasiglucagon	Diabetes	J3490	06/07/2021
Zembrace SymTouch	sumatriptan succinate	Serotonin 5HT-1 Receptor Agonists	J3490	3/09/2016
Zepbound	tirzepatide	Human GLP-1 Analogs	J3490	11/08/2023
Zilbrysc	zilucoplan	Nervous System Disorders, Other	J3490	10/17/2023
Zimhi	naloxone hydrochloride	Opioid antagonist	J2311	01/01/2023
Zomacton	somatropin	Anabolic Hormones	J2941	09/28/2017
Zorbtive	somatropin	Anabolic Hormones	J2941	1/1/2010
Zurnai	nalmefene	Opioid antagonist	J3490	08/07/2024
Zymfentra *(for subcutaneous use)* *Note: For Intravenous use of Infliximab covered under the medical benefit, please refer to* *policy 08.00.34 Intravenous Infliximab and Related Biosimilars*	infliximab-dyyb	Monoclonal Antibodies	J1748	10/20/2023

Version Effective Date: 01/01/2025

Field Name	Field Description
Prior Authorization Group Description	**Spravato**
Drugs	**Spravato** (esketamine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patients must be 18 years age or older
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the initial request will be approved for 4 weeks. For continuation of therapy the request will be approved for 6 months.

Other Criteria	**Initial Authorization:**
	• Member has a diagnosis of at least one of the following:
	  o Major depressive disorder with treatment-resistant depression
	  o Major depressive disorder with acute suicidal ideation or behavior
	• Medication is being prescribed at an FDA approved dosage.
	• If Spravato is being requested for a diagnosis of major depressive disorder with treatment-resistant depression (i.e. without suicidal ideation or behavior) the member has either:
	  o Documented trial and failure of two preferred oral antidepressants (eg. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer
	  OR
	  o Medical justification as to why the patient cannot use preferred alternative(s).
	• Requests for a diagnosis of major depressive disorder with acute suicidal ideation or behavior (not required for treatment resistant depression):
	  o Prescriber attests Spravato will be used in conjunction with an oral antidepressant
	
	Re-authorization:
	• Medication is prescribed at an FDA-approved dosage.
	• Medication is being used in conjunction with an oral antidepressant (not required for diagnosis of treatment resistant depression).
	• Documentation was submitted indicating the member has clinically benefited from therapy.

Revision/Review Date 11/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Title: Sutimlimab-jome (Enjaymo)

MEDICALLY NECESSARY

SUTIMLIMAB-JOME (ENJAYMO)

Sutimlimab-jome (Enjaymo) is considered medically necessary and, therefore, covered for the treatment of hemolysis in adult individuals with cold agglutinin disease (CAD) when all of the following criteria are met:

- The individual confirmed diagnosis of primary cold agglutinin disease (CAD) based on all of the following criteria:
    - Chronic hemolysis
    - Polyspecific direct antiglobulin test (DAT) positive
    - Monospecific DAT is strongly positive for C3d
    - Cold agglutinin titer >= 64 at 4 degrees Celsius
    - Immunoglobulin G (IgG) DAT less than or equal to (<=) 1+
    - No overt malignant disease (e. i., an aggressive or malignant disease that is easily observable; clinically obvious; symptomatic, and often rapid organ damage)
- History of at least one documented blood transfusion within six months of treatment
- Hemoglobin level <= 10.0 gram per deciliter (g/dL)
- Bilirubin level above the normal reference range, including individuals with Gilbert's Syndrome
- The individual has a bodyweight of greater than or equal to (>=) 39 kilogram (kg) at the initiation of the treatment

- The individual does **not** have any of the following conditions:
    - Cold agglutinin syndrome secondary to an infection, rheumatologic disease, or active hematologic malignancy
    - Clinically relevant infection of any kind within the month preceding treatment (eg, active hepatitis C, pneumonia)
    - Clinical diagnosis of systemic lupus erythematosus (SLE) or other autoimmune disorders with anti-nuclear antibodies at the initiation of the treatment.

- The individual has all of the following:
    - Negative hepatitis panel (including hepatitis B surface antigen and/or hepatitis C virus antibody) prior to or at the initiation of the treatment
    - Negative human immunodeficiency virus (HIV) antibody at the initiation of the treatment
    - Vaccination against encapsulated bacteria at least two weeks prior to the treatment

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Field Name	Field Description
Prior Authorization Group Description	**Synagis (palivizumab)**
Drugs	Synagis (palivizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members who have received Beyfortus (nirsevimab-alip) for the current respiratory syncytial virus (RSV) season
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	A maximum of 5 doses may be approved within the Respiratory Syncytial Virus (RSV) season. Requests for additional doses will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.
Other Criteria	Must have documented medical reason for not using Beyfortus (niresvimab) AND Infants less than 1 year of age at the onset of the respiratory syncytial virus (RSV) season (which typically starts November 1st, but may vary seasonally) **AND** have one of the following indications: • Born at less than 29 weeks, 0 days gestation • Born at less than 32 weeks, 0 days gestation AND had chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth • Born at any gestational age with hemodynamically significant heart disease including: o Cyanotic heart disease in consultation with a pediatric cardiologist o Acyanotic Heart disease with one of the following: ▪ On heart failure medication and expected to require cardiac surgical procedure ▪ Moderate to severe pulmonary hypertension • Cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life • Born at any gestational age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airway

Revision/Review Date: 11/2025	Infants less than 2 years of age at the onset of the RSV season (which typically starts November 1st, but may vary seasonally) **AND** have one of the following indications:
	• Born at less than 32 weeks, 0 days AND had a diagnosis of chronic lung disease of prematurity at birth as defined above **AND** had continued need for one of the following respiratory interventions in the 6 months preceding RSV season: Chronic steroids, chronic diuretics, supplemental oxygen
	• Cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile
	• Born at any gestational age and will be profoundly immunocompromised during the RSV season, including:
	  ○ Solid organ or hematopoietic stem cell transplant recipient
	  ○ Chemotherapy recipient
	• Born at any gestational age and receiving a cardiac transplant
	
	Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.

Title: Teplizumab-mzwv (Tzield)

MEDICALLY NECESSARY

Teplizumab-mzwv (Tzield) is considered medically necessary and, therefore, covered to delay the onset of Stage 3 type 1 diabetes (T1D) in adult and pediatric individuals eight years and older who currently have stage 2 type 1 diabetes when all of the following criteria are met, including dosing and frequency:

- Prescribed by or in consultation with endocrinologist
- The individual has abnormal oral glucose tolerance by OGTT defined by one of the following:
    - Fasting glucose 100 to 125 milligrams per deciliter (mg/dL) / 5.6 to 6.9 millimoles per liter (mmol/L)
    - Two-hour postprandial glucose 140 to 199 mg/dL / (7.8 to 11.1 mmol/L)
    - A1C 5.7 to 6.4 percent
- The individual has the presence of at least two confirmed diabetes autoantibodies detected in two samples obtained within 6 months before initiation of the treatment (e.g., glutamic acid decarboxylase 65 [GAD] autoantibodies, insulin autoantibody [IAA], insulinoma-associated antigen 2 autoantibody [IA-2A], zinc transporter 8 autoantibody [ZnT8A], islet cell autoantibody [ICA])
- The individual does NOT have any of the following:
    - Stage 3 type 1 diabetes (e.g., excessive hunger or thirst, blurry vision, severe fatigue, frequent urination, unexplained weight loss)
    - Clinical history consistent with type 2 diabetes
- Dosing and frequency for teplizumab-mzwv (Tzield) intravenous infusion one treatment course (i.e., 14 doses) per lifetime:
    - Day one: 65 mcg/m^2
    - Day two: 125 mcg/m^2
    - Day three: 250 mcg/m^2
    - Day four: 500 mcg/m^2

- Days five through 14: 1,030 mcg/m^2

EXPERIMENTAL/INVESTIGATIONAL

All other uses for teplizumab-mzwv (Tzield) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

DOSING AND FREQUENCY REQUIREMENTS

The Company reserves the right to modify the Dosing and Frequency Requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of teplizumab-mzwv (Tzield). Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to: the US Food and Drug Administration (FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of teplizumab-mzwv (Tzield) outside of the Dosing and Frequency Requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the utilization management activities. The Company reserves the right to conduct postpayment review and audit procedures for any claims submitted for teplizumab-mzwv (Tzield).

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

When coverage of teplizumab-mzwv (Tzield) is requested outside of the Dosing and Frequency Requirements listed in this policy, the prescribing professional provider must supply

documentation (i.e., published peer-reviewed literature) to the Company that supports this request.

Duration of authorization: 14 days

Version Effective Date: 05/2026

Title: Teprotumumab-trbw (Tepezza®)

MEDICALLY NECESSARY

Teprotumumab-trbw (Tepezza) is considered medically necessary and, therefore, covered for adult individuals with active or inactive thyroid eye disease who have a confirmed diagnosis of Graves' disease, when all of the following criteria listed below are met, including dosing and frequency:

- Individual has moderate to severe thyroid eye disease (TED) with documentation of one or more of the following:
    - lid retraction ≥2 mm
    - moderate or severe soft-tissue involvement
    - proptosis ≥3 mm above normal values, as determined by professional provider
    - periodic or constant diplopia
- Individual has documentation of symptomatic TED, characterized by one or more of the following symptoms:
    - dry eye
    - exposure keratitis
    - inflammation, pain, or redness of the eye/eyelids
    - lagophthalmos (incomplete or defective closure of the eyelids) with excessive lacrimation
    - strabismus
- Individual is euthyroid or with mild hypo- or hyperthyroidism defined as free thyroxine (FT4) and free tri-iodothyronine (FT3) levels less than 50% above or below the normal limits.
- Individual does not have planned surgical ophthalmological intervention for proptosis repair
- Prescribed by an ophthalmologist, or endocrinologist in consultation with an ophthalmologist

- Dosing and Frequency: 10 mg/kg for first infusion, followed by 20 mg/kg every 3 weeks for seven additional infusions (maximum of eight doses or one cycle)

Duration of authorization: 12 months

Version Effective Date: 2/2026

Title: Tildrakizumab-asmn (Ilumya®)

MEDICALLY NECESSARY

Tildrakizumab-asmn (Ilumya) is considered medically necessary and, therefore, covered for adult individuals with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, when the following criteria listed below are met:

- Individual has been diagnosed with moderate-to-severe plaque psoriasis for at least 6 months
- There is documentation of failure, contraindication, or intolerance to a trial of at least one of the following:
    - Systemic agent (e.g., immunosuppressives, retinoic acid derivatives, and/or methotrexate)
    - Phototherapy (i.e., psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol)
    - Topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or vitamin D analogues)
- Active or latent tuberculosis (TB) has been ruled out
- Individuals will not be treated with live vaccine(s) during treatment with tildrakizumab-asmn (Ilumya)

EXPERIMENTAL/INVESTIGATIONAL

All other uses of tildrakizumab-asmn (Ilumya) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Duration of authorization: 12 months

Version Effective Date: 2/2026

Title: Tocilizumab (Actemra®) and Related Biosimilars for Intravenous Infusion

MEDICALLY NECESSARY

INITIAL THERAPY
Tocilizumab (Actemra) and related biosimilars for intravenous infusion are considered medically necessary and, therefore, covered for the following indications when, for each individual indication, all of the associated criteria are met:

Castleman disease (CD)

- In one of the following conditions, as a single agent:
    - Multicentric CD: Subsequent therapy for multicentric CD that has progressed following treatment of relapsed/refractory or progressive disease
    - Unicentric CD: Second-line therapy for individuals with relapsed or refractory disease who are human immunodeficiency virus–negative and human herpesvirus-8–negative
- Active or latent tuberculosis (TB) has been ruled out

Coronavirus disease 2019 (COVID-19)

- In individuals 2 years of age or older who are hospitalized with coronavirus disease 2019 (COVID-19)
- In conjunction with systemic corticosteroids and require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)
- Active or latent TB has been ruled out

Cytokine release syndrome (CRS) caused by chimeric antigen receptor (CAR) T-cell therapy (e.g., axicabtagene ciloleucel [Yescarta], brexucabtagene autoleucel [Tecartus], lisocabtagene maraleucel [Breyanzi], tisagenlecleucel [Kymriah])

- In individuals 2 years of age or older
- When used alone or in combination with corticosteroids
- When used for the following grades, per National Cancer Institute's Common Terminology criteria for Adverse Events (CTCAE v5.0) Grading System*:
    - CRS Grades 2–4

    - CRS symptoms that persist for more than 24 hours in individuals treated with axicabtagene ciloleucel (Yescarta) or brexucabtagene autoleucel (Tecartus)
    - For prolonged (>3 days) Grade 1 CRS in individuals with significant symptoms, comorbidities, and/or in elderly individuals
    - Grade 1 CRS that develops less than 72 hours after infusion in those treated with lisocabtagene maraleucel (Breyanzi); for CRS that develops more than 72 hours after infusion, treat symptomatically
- Active or latent TB has been ruled out
- When used up to a maximum of four doses
- Giant cell arteritis (GCA)

- In individuals 18 years of age or older

- There is documentation of inadequate response, intolerance, or contraindication to systemic corticosteroids
- Active or latent TB has been ruled out

Graft-versus-host disease (GVHD), acute, after hematopoietic cell transplantation

- In conjunction with systemic corticosteroids and/or immunosuppressive agent following no response (steroid-refractory disease) to first-line therapy options

- Active or latent TB has been ruled out
- Polyarticular juvenile idiopathic arthriti (pJIA),active
- For individuals who have not previously received a biologic disease-modifying antirheumatic drug (DMARD) to treat pJIA, tocilizumab (Actemra) and related biosimilars for intravenous infusion are only eligible for coverage when the individual has a documented failure, contraindication, or intolerance to golimumab (Simponi Aria), or there is a clinical reason that a trial of golimumab (Simponi Aria) would be otherwise inappropriate for the individual.
- In individuals 2 years of age or older
- Active or latent TB has been ruled out
- When used alone or in combination with methotrexate
- There is documentation of inadequate response, intolerance, or contraindication to nonbiologic DMARDs (e.g., methotrexate)

Rheumatoid arthritis

- For individuals who have not previously received a biologic DMARD to treat adult rheumatoid arthritis, tocilizumab (Actemra) and related biosimilars for intravenous infusion are only eligible for coverage when the individual has a documented failure, contraindication, or intolerance to infliximab (Remicade) or golimumab (Simponi Aria), or there is a clinical reason that a trial of infliximab (Remicade) or golimumab (Simponi Aria) would be otherwise inappropriate for the individual.
- Moderately to severely active disease
- In individuals 18 years of age or older
- Active or latent TB has been ruled out
- When used alone or in combination with methotrexate or other nonbiologic DMARDs
- There is documentation of inadequate response, intolerance, or contraindication to a 3-month trial of one or more DMARDs

Systemic juvenile idiopathic arthritis (SJIA), active

- In individuals 2 years of age or older
- Active or TB has been ruled out
- When used alone or in combination with methotrexate
- There is documentation of inadequate response, intolerance, or contraindication to nonsteroidal anti-inflammatory drugs (NSAIDS), corticosteroids, or DMARDs (e.g., leflunomide, methotrexate)

*See Guidelines Section for Grading Tables for CRS and neurotoxicity.

CONTINUATION THERAPY

Tocilizumab (Actemra) and related biosimilars are considered medically necessary and, therefore, covered for continuation therapy when the individual meets all of the following:

- The individual has met the medical necessity criteria for Initial Therapy
- There is documentation of a positive clinical response or stabilization to therapy (e.g., improvement in total active [swollen and tender] joint count from baseline, improvement in symptoms [e.g., pain, stiffness, inflammation, fever, fatigue, nonproductive cough] from baseline)

EXPERIMENTAL/INVESTIGATIONAL

All other uses for tocilizumab (Actemra) and related biosimilars for intravenous infusion are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

BILLING REQUIREMENTS

For drugs that have more than one method of administration, application of the JA modifier is required to indicate the route of administration.

- To report the intravenous route of administration, append the following modifier: JA Administered Intravenously

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, utilization management/referral requirements, provider contracts, and Company policies apply.

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Treatments for Complex Regional Pain Syndrome (CRPS)

MEDICALLY NECESSARY

The following interventions are considered medically necessary, and, therefore, covered, for treatment of complex regional pain syndrome (CRPS) when their respective criteria are met:

- Local anesthetic sympathetic nerve blocks (i.e., stellate ganglion block for upper extremity pain or lumbar sympathetic block for lower extremity pain) related to CRPS when first-line pain management strategies (e.g., oral medications [e.g, nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, opioids, antiepileptics, antidepressants, clonidine, muscle relaxants], physical therapy, or occupational therapy) tried for at least a 2-week period have failed to diminish or eliminate the individual's pain.
    - Following a positive response to the initial diagnostic stellate ganglion block, and sustained benefit in pain and function after three sympathetic blocks from baseline (preblock) pain and function; additional regional sympathetic blocks of up to a maximum of six total blocks in a 12-month period, performed at a frequency of no more than two per week, are considered medically necessary, and, therefore, covered when all the following criteria have been met:
        - Benefit has been demonstrated by prior blocks as evidenced by all of the following:
            - Decreased use of pain medication
            - Improved level of function (e.g., increased range of motion, strength, and use of extremity in activities of daily living)
            - Improved tolerance to touch (e.g., decreased allodynia) or other objective measures
        - The intervention is being provided as part of a comprehensive pain management program (physical therapy, patient education, psychosocial support, and oral medication).
- Epidural or intrathecal opioids: A preliminary trial of opioid drug administration for the treatment of severe, chronic, intractable pain via a temporary intrathecal/epidural catheter is indicated for individuals who are unresponsive to less-invasive medical therapy such as orally administered systemic opioids and/or nerve blocks with local anesthetics and steroids.
    - If this preliminary trial demonstrates pain relief and a degree of side effects that are adequately acceptable (including effects on activities of daily living) and has

the individual's acceptance, a permanent implantable infusion pump may be considered for continuous intrathecal or epidural administration of opioids.

    - The drug being administered and the purpose of its administration must be consistent with the indicated uses in the pump's US Food and Drug Administration (FDA)–approved labeling.
    - The individual has a life expectancy of at least 3 months.

- Intrathecal ziconotide (Prialt®): The administration of intrathecal ziconotide (Prialt®) is indicated for the management of severe chronic pain in individuals for whom intrathecal therapy is warranted and who are intolerant of, or refractory to, other treatments such as systemic analgesics (e.g., NSAIDs, opioids, antiepileptics, antidepressants) adjunctive therapies (e.g., physical therapy, nerve blocks, spinal cord stimulation), or intrathecal morphine.
- Intrathecal baclofen: A preliminary trial of intrathecal baclofen is indicated when pain is caused by spasticity for individuals who are unresponsive to, or intolerant of, at least a 6-week trial of noninvasive medical therapy, such as orally administered antispasmodic drugs.
    - If this preliminary trial demonstrates pain relief and a degree of side effects that are adequately acceptable (including effects on activities of daily living) and has the individual's acceptance, a permanent implantable infusion pump may be considered for continuous intrathecal or epidural administration of opioids.
    - The drug being administered and the purpose of its administration must be consistent with the indicated uses in the pump's FDA-approved labeling.

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Triamcinolone Acetonide Extended-Release Injectable (Zilretta®)

MEDICALLY NECESSARY

Triamcinolone Acetonide Extended-Release (ER) Injectable (Zilretta) is considered medically necessary and, therefore, covered when all of the following criteria are met:

- The individual is 18 years of age or older
- The individual has a documented diagnosis of osteoarthritis of the knee
- The individual has not previously been treated with triamcinolone acetonide ER injectable (Zilretta)
- The individual has a documented inadequate response to conservative non-pharmacologic therapy (e.g., weight loss, strengthening and range of motion exercises, etc)
- The individual has a documented failure of, contraindication to, or inadequate response to at least a two-week trial of oral or topical non-steroidal anti-inflammatory drugs (NSAIDs) or tramadol
- The individual has a documented inadequate response to previous treatment with intra-articular steroid injection (triamcinolone, methylprednisolone, betamethasone, dexamethasone)
- The dose does not exceed 32 mg as a single intra-articular injection to the knee

EXPERIMENTAL/INVESTIGATIONAL

All other uses for triamcinolone acetonide ER injectable (Zilretta), **including repeat administration into same knee**, are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Trilaciclib (Cosela™)

MEDICALLY NECESSARY

TRILACICLIB (COSELA™)

Initial Therapy

Trilaciclib (Cosela) is considered medically necessary and, therefore, covered when used to decrease the incidence of chemotherapy-induced myelosuppression in adult individuals and one of the following criteria are met:

- Administered prior to a platinum/etoposide-containing regimen
- Administered prior to topotecan-containing regimen for extensive-stage (when cancer has spread beyond the lungs) small cell lung cancer (ES-SCLC).

Continuation Therapy

Trilaciclib (Cosela) is considered medically necessary and, therefore, covered for continuation therapy when the initial criteria are met, until disease progression or death.

EXPERIMENTAL/INVESTIGATIONAL

All other uses for trilaciclib (Cosela) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include but are not limited to: records from the professional provider's

office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Ublituximab-xiiy (Briumvi®) for intravenous use

MEDICALLY NECESSARY

Ublituximab-xiiy (Briumvi®) is considered medically necessary and, therefore, covered for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome (CIS), relapsing-remitting multiple sclerosis (RRMS), and active secondary progressive multiple sclerosis (SPMS), in adults when **all** of the following are met:

- The individual has a confirmed diagnosis of relapsing MS (RMS)
- The individual does not have a diagnosis of primary progressive MS (PPMS)

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Ustekinumab (Stelara®)

Policy

Coverage is subject to the terms, conditions, and limitations of the member's contract.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

INITIAL THERAPY WITH USTEKINUMAB (STELARA)

CROHN'S DISEASE AND ULCERATIVE COLITIS
Ustekinumab (Stelara) is considered medically necessary and, therefore, covered for the treatment of individuals with moderate-to-severe active Crohn's disease or moderate-to-severe active ulcerative colitis when both of the following criteria and the Dosing and Frequency Requirements listed below are met:

- The individual is at least 18 years of age.
- There is documentation of failure, contraindication, or intolerance to a trial of one of the following:
    - Immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate)
    - Corticosteroids (e.g., budesonide [Entocort EC], prednisone, hydrocortisone, methylprednisolone)
    - Biologic therapy (e.g., certolizumab [Cimzia], adalimumab [Humira], infliximab [Remicade]), vedolizumab [Entyvio])

IMMUNE-CHECKPOINT INHIBITOR-RELATED TOXICITY MANAGEMENT

Ustekinumab (Stelara) is considered medically necessary and, therefore, covered for the management of the following autoimmune-like toxicities (also known as immune-related adverse events), when other etiologies have been ruled out and any of the following criteria and the Dosing and Frequency Requirements listed below are met:

- Mild (Grade 1) diarrhea or colitis if persistent or progressive symptoms after standard symptomatic treatments and positive lactoferrin/calprotectin
- Infliximab- and/or vedolizumab-refractory moderate (Grade 2) or severe (Grade 3-4) diarrhea or colitis

PLAQUE PSORIASIS

Ustekinumab (Stelara) for subcutaneous injection is considered medically necessary and, therefore, covered for the treatment of individuals with moderate-to-severe chronic plaque

psoriasis who are candidates for systemic therapy or phototherapy, when both of the following criteria and the Dosing and Frequency Requirements listed below are met:

- The individual is at least 6 years of age.
- There is documentation of failure, contraindication, or intolerance to a trial of at least one of the following:
    - Topical steroids
    - Topical nonsteroids (e.g., topical calcipotriene [Dovonex], topical anthralin, topical retinoids [Tazorac])
    - Topical immune modulators (e.g., Elidel, Protopic)
    - Methotrexate (MTX) (e.g., Trexall, Rheumatrex)
    - Retinoids (e.g., acitretin [Soriatane])
    - Cyclosporine (e.g., Neoral, Gengraf)

PSORIATIC ARTHRITIS

Ustekinumab (Stelara) for subcutaneous injection is considered medically necessary and, therefore, covered when used alone or in combination with MTX for the treatment of individuals with active psoriatic arthritis when both of the following criteria and the Dosing and Frequency Requirements listed below are met:

- The individual is at least 6 years of age.
- Documented failure, contraindication, or intolerance to a trial of at least one disease-modifying antirheumatic drug (DMARD) that include but are not limited to the following:
    - Sulfasalazine (e.g., Azulfidine)
    - Azathioprine (e.g., Imuran)
    - Hydroxychloroquine
    - Cyclosporine (e.g., Neoral, Gengraf)
    - Methotrexate (e.g., Trexall, Rheumatrex)
    - Anti–tumor necrosis factor agents

CONTINUATION THERAPY WITH USTEKINUMAB (STELARA)

Continuation therapy is considered medically necessary and, therefore, covered when the

individual has met the coverage criteria for Initial Therapy, and the treatment with ustekinumab (Stelara) resulted in documented improvement of symptoms or functions of affected areas.

DOSING AND FREQUENCY OF ADMINISTRATION

The following dosage and frequency information was taken from the Prescribing Information for this product at the time the policy was being developed:

CROHN'S DISEASE, ULCERATIVE COLITIS, AND IMMUNE-CHECKPOINT INHIBITOR–RELATED TOXICITY MANAGEMENT (DIARRHEA, COLITIS)

- For initial intravenous infusion:
    - For persons whose weight is up to 55 kg, the recommended dose is 260 mg (two vials).
    - For persons whose weight is more than 55 kg to 85 kg, the recommended dose is 390 mg (three vials).
    - For persons whose weight is more than 85 kg, the recommended dose is 520 mg (four vials).
- For subcutaneous injection as maintenance treatment:
    - The recommended dose is 90 mg 8 weeks after the initial intravenous dose, then every 8 weeks thereafter (for immune-checkpoint inhibitor–related toxicities, for a maximum of three maintenance doses).

PSORIASIS: subcutaneous injection

Adults:

- For persons whose weight is 100 kg (220 lbs) or less, the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
- For persons whose weight is more than 100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

Pediatrics 6–17 years of age:

- For persons whose weight is less than 60 kg (132 lbs), the recommended dose is 0.75 mg/kg initially, 4 weeks later, followed by 0.75 mg/kg every 12 weeks.
- For persons whose weight is 60 kg to 100 kg (132–220 lbs), the recommended dose is 45 mg initially, 4 weeks later, followed by 45 mg every 12 weeks.

- For persons whose weight is more than 100 kg (220 lbs), the recommended dose is 90 mg initially, 4 weeks later, followed by 90 mg every 12 weeks.

PSORIATIC ARTHRITIS: SUBCUTANEOUS INJECTION

Adults:

- The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
- For persons with coexistent moderate-to-severe plaque psoriasis who weigh greater than 100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

Pediatrics 6–17 years of age:

- For persons whose weight is less than 60 kg (132 lbs), the recommended dose is 0.75 mg/kg initially, 4 weeks later, followed by 0.75 mg/kg every 12 weeks.
- For persons whose weight is 60 kg (132 lbs) or more, the recommended dose is 45 mg initially, 4 weeks later, followed by 45 mg every 12 weeks.
- For persons whose weight is more than 100 kg (220 lbs) with coexistent moderate-to severe plaque psoriasis, the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

Duration of authorization: 12 months
P&T Approval Date: 11/2025

Title: Vedolizumab (Entyvio®) for Injection for Intravenous Use

MEDICALLY NECESSARY

Vedolizumab (Entyvio) is considered medically necessary and, therefore, covered when all of the following criteria, including Dosing and Frequency Requirements listed below, are met for any of the following indications:

ULCERATIVE COLITIS (UC)

- In adult individuals with moderately to severely active UC who meet all of the following criteria:
    - Inadequate response, lost response, or intolerance to a 3-month trial of a tumor necrosis factor (TNF) blocker (e.g., adalimumab Humira®) or immunomodulator (e.g., azathioprine, 6-mercaptopurine), or inadequate response to, intolerance of, or demonstrated dependence on, corticosteroids
    - Vedolizumab (Entyvio) is dosed at 300 mg intravenous (IV) infusion at 0, 2, and 6 weeks, and then every 8 weeks thereafter. The US Food and Drug Administration (FDA) labeling indicates that therapy be discontinued in individuals who show no evidence of therapeutic benefit by Week 14.

CROHN'S DISEASE (CD)

- In adult individuals with moderately to severely active CD who meet all of the following criteria:
    - Inadequate response with, lost response to, or were intolerant of, a 3-month trial of a tumor necrosis factor (TNF) blocker (e.g., adalimumab Humira) or immunomodulator (e.g., azathioprine, 6-mercaptopurine, methotrexate), or had an inadequate response with, were intolerant to, or demonstrated dependence on, corticosteroids
    - Vedolizumab (Entyvio) is dosed at 300 mg IV infusion at 0, 2, and 6 weeks, and then every 8 weeks thereafter. The FDA labeling indicates that therapy should be discontinued in individuals who show no evidence of therapeutic benefit by Week 14.

MANAGEMENT OF IMMUNOTHERAPY-RELATED TOXICITIES

Immune Checkpoint Inhibitor–Related Toxicities

- In adult individuals with an immune checkpoint inhibitor (e.g., ipilimumab, nivolumab)–related diarrhea and or colitis who meet all of the following criteria:
    - The individual has any of the following immunotherapy-related toxicities:
        - moderate grade two (G2) diarrhea or colitis (defined as four to six bowel movements above baseline per day, colitis symptoms, not interfering with activities of daily living [ADLs])
        - severe (G3-4) diarrhea or colitis (Severe diarrhea [grade 3] is defined as ≥7 stools per day above baseline, and grade 3 colitis is defined by the presence of peritoneal signs with ileus and fever consistent with bowel perforation. A grade 4 designation is distinct from grade 3, reflecting increased severity and the life-threatening nature of symptoms).
    - Vedolizumab (Entyvio) is dosed at 300 mg IV infusion at 0, 2, and 6 weeks (induction only)

Duration of authorization: 12 months

P&T Approval Date: 11/2025

Title: Velmanase alfa (Lamzede)

MEDICALLY NECESSARY

Initial criteria

Velmanase alfa-tycv (Lamzede) is considered medically necessary and, therefore, covered for the treatment of non-central nervous system manifestations (i.e., skeletal abnormalities, myopathy, motor function disturbances, immunodeficiency, etc.) of alpha-mannosidosis (AM) in pediatric and adult individuals when all of the following criteria are met, including dosing and frequency:

- Prescribed by or in consultation with a geneticist or metabolic specialist

- Diagnosis is confirmed by either of the following:
    - Confirmation of diagnosis by biochemical assay showing decreased alpha-mannosidase activity in white blood cells or skin fibroblasts less than 10 percent of normal values

    - Genotyping revealing two pathogenic mutations of the MAN2B1 gene
- Documented baseline age-appropriate values for one or more of the following:
    - 6-minute walk test (6-MWT),
    - 3-minute stair climb test (3-MSCT),
    - pulmonary function tests (e.g., forced vital capacity[FVC]),
    - motor function (i.e., Bruininks-Oseretsky Test of Motor Proficiency [BOT-2])
- The individual does **not** have any of the following :
    - A history of a hematopoietic stem-cell transplantation (HSCT) or bone marrow transplant
    - The individual cannot walk without support
- Dosing and frequency: children, adolescents and adults dosing intravenous infusion : 1 mg/kg once every week

NOTE: For very young individuals in which FVC or 6-MWT are not suitable for measuring, requests will be reviewed on a case-by case basis.

Continuation criteria:

- The individual continues to meet the initial criteria
- The individual has demonstrated a beneficial response to therapy or stabilization of disease compared to pretreatment age-appropriate baseline values in one or more of the following:

    - Stability or improvement in serum oligosaccharide concentration
    - Stability or improvement in 6-minute walking test (6-MWT)
    - Stability or improvement in 3-minute stair climbing test (3-MSCT)
    - Stability or improvement in forced vital capacity (FVC) (% predicted)
    - Stabilization or slowing in the rate of disease progression or clinical decline

EXPERIMENTAL/INVESTIGATIONAL

All other uses of velmanase alfa-tycv (Lamzede) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

DOSING AND FREQUENCY REQUIREMENTS

The Company reserves the right to modify the Dosing and Frequency Requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of velmanase alfa-tycv (Lamzede). Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to: the US Food and Drug Administration (FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of velmanase alfa-tycv (Lamzede) outside of the Dosing and Frequency Requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the utilization management activities. The Company reserves the right to conduct post-payment review and audit procedures for any claims submitted for velmanase alfa-tycv (Lamzede).

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

When coverage of velmanase alfa-tycv (Lamzede) is requested outside of the Dosing and Frequency Requirements listed in this policy, the prescribing professional provider must supply documentation (i.e., published peer-reviewed literature) to the company that supports this request.

Duration of authorization: 12 months

Version Effective Date: 05/2026

Title: Voretigene Neparvovec-rzyl (Luxturna®)

MEDICALLY NECESSARY

Voretigene neparvovec-rzyl (Luxturna) is considered medically necessary and, therefore, covered for the treatment of individuals with confirmed biallelic *RPE65* variation(s) causing retinal dystrophy who are experiencing vision loss when all of the following criteria are met:

- Documentation of laboratory results confirming biallelic *RPE65* variation(s) causing retinal dystrophy
- The individual has viable retinal cells, as determined by the treating retinal specialist, and characterized by at least one of the following features:
    - An area of retina within the posterior pole of >100 µm thickness shown on optical coherence tomography
    - ≥3 Disc areas of retina without atrophy or pigmentary degeneration within the posterior pole
    - Remaining visual field within 30° of fixation as measured by III4e isopter or equivalent
- Age of individual is 3 years and older
- Administration will occur at a certified treatment center staffed with professional providers, including retinal specialists, who have experience treating individuals with inherited retinal diseases
- Individual does not have any of the following exclusion criteria:
    - Use of high-dose (>7500 retinol equivalent units [or >3300 IU] per day of vitamin A) retinoid compounds in the past 18 months
    - Intraocular surgery in the past 6 months
    - Ocular or systemic conditions that would interfere with this gene therapy
    - Pregnant individuals or individuals of child-bearing potential who are unwilling to use effective contraception for 4 months after vector administration

Duration of authorization: n/a

P&T Approval Date: 05/2026